IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO, WESTERN DIVISION

KEVIN SCHWARTZ and STEPHANIE SCHWARTZ, *Plaintiffs,* v. PURDUE PHARMA L.P., PURDUE PHARMA, INC., PURDUE FREDERICK COMPANY, RHODES PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS, INC., and ENDO PHARMACEUTICALS, INC., *Defendants.*	Case No.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Kevin Schwartz and Stephanie Schwartz bring this Complaint and Demand for Jury Trial to obtain redress in the form of monetary and injunctive relief from the Defendants named herein for their fraudulent promotion of opioids for long-term use and the harm these actions caused Plaintiffs. Plaintiffs, for their Complaint, allege as follows upon personal knowledge as to themselves and their own acts and experiences, and, as to all other matters, upon information and belief:

NATURE OF THE ACTION

1. In January of 2001, Plaintiff Kevin Schwartz injured his back after slipping on a patch of ice in a parking lot. He was prescribed oxycodone, a powerful opioid, to treat his pain.

2. In the five years after his fall, Mr. Schwartz was prescribed increasing doses of oxycodone and other opioid-based pain medication. He developed an ever-worsening opioid addiction, and as a result, lost interest in virtually everything he had once loved. He lost touch

with most of his friends and family, and his relationship with his wife, Plaintiff Stephanie Schwartz, deteriorated to the point that she nearly filed for divorce.

3. Even after Mr. Schwartz overcame his opioid addiction, his suffering continued. As a direct result of his long-term opioid use, Mr. Schwartz was diagnosed with kidney cancer.

4. Prescription opioids have devastated communities across the United States and Ohio, as has been well-documented. The ongoing opioid epidemic, and Kevin Schwartz's addiction, is the direct result of the Defendants' deliberate campaign of deception.

5. For years, Defendants—manufacturers of prescription opioids—misrepresented the risks and benefits posed by the opioids they manufacture and sell, misleading susceptible prescribers and vulnerable patient populations. As families and communities like Kevin Schwartz's suffered from the scourge of opioid abuse, Defendants earned billions in profits as a direct result of the harms they caused.

6. Defendants knew their misrepresentations about the risks and benefits of opioids were not supported by, and were sometimes directly contrary to, the scientific evidence. Nonetheless, Defendants continued to misrepresent the risks and benefits of long-term opioid use across the U.S., including in Ohio and Plaintiffs' community in Toledo.

7. Defendants' false and misleading conduct deceived doctors in the Toledo area, as well as patients like Kevin Schwartz, about the risks and benefits of opioids, convincing them that opioids were not only appropriate, but *necessary* to treat chronic pain for long periods of time. They did so in part by tainting the sources doctors and patients rely upon for guidance, including treatment guidelines, medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat chronic pain like Kevin Schwartz's, opening the floodgates for unnecessary opioid prescriptions

and dependence.

8. The explosion in opioid prescriptions and use has created a public health crisis in Ohio. Their widespread use has created a population of addicted and dependent patients—including Kevin Schwartz, who became addicted to opioids as a direct consequence of Defendants' false and misleading conduct.

9. This action seeks to hold Defendants accountable for the addiction, health costs, and other harms they have imposed on Kevin Schwartz, and the loss of consortium it caused for his wife, Stephanie Schwartz.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1322(a)(1) because Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interests and costs. Plaintiffs are citizens of Ohio, while Defendants are, variously, citizens of Delaware, New York, Connecticut, and Pennsylvania.

11. This Court has personal jurisdiction over Defendants because Plaintiffs' claims arise out of or relate to Defendants' contacts with Ohio. For example, Defendants knowingly and intentionally sell, market, advertise, promote, and distribute their products throughout the State of Ohio and to Ohio residents and businesses. Defendants have directed advertising, marketing, and promotional efforts at Ohio and Ohio residents and doctors. And, above all, Defendants have delivered, distributed, and sold opioids in Ohio with the intent and/or expectation that those products would be distributed to or purchased by Ohio residents.

12. Venue is proper in this District because a substantial part of the events giving rise to Plaintiffs' claims occurred in, were directed to, and/or emanated from this District. 28 U.S.C.

§ 1391(b).

PARTIES

13. Plaintiff Kevin Schwartz is a natural person and resident of the State of Ohio.

14. Plaintiff Stephanie Schwartz is a natural person and resident of the State of Ohio.

15. Defendant Purdue Pharma L.P. ("Purdue L.P.") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma, Inc. ("Purdue Inc.") is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. ("Purdue Frederick") is a New York corporation with its principal place of business in Stamford, Connecticut. Rhodes Pharmaceuticals, L.P. ("Rhodes") is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. These four entities are collectively referred to herein as "Purdue" unless otherwise specified.

16. Endo Health Solutions, Inc. ("Endo Health Solutions") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. d/b/a Endo Generic Products ("Endo Pharmaceuticals") is a wholly owned subsidiary of Endo Health Solutions and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

17. Endo Health Solutions and Endo Pharmaceuticals are collectively referred to herein as "Endo," unless otherwise specified.

FACTUAL ALLEGATIONS

I. Prescription Opioids Are Dangerous Narcotics With No Demonstrated Use For Treating Chronic Non-Cancer Pain, And Are At The Center Of An Epidemic.

18. To explain the nature of Defendants' illegal conduct, it is first necessary to explain how prescription opioids work—and don't—in order to understand how they sparked an

ongoing epidemic of addiction affecting thousands of Ohioans, including Plaintiff Kevin Schwartz and his spouse, Plaintiff Stephanie Schwartz.

A. Background on Prescription Opioids.

19. The term opioid means "opium-like," and includes all drugs derived in whole or in part from the opium poppy.

20. In the medical field, opioids are a class of drugs and analgesic (*i.e.*, pain-relieving) agents that include pain relief drugs obtainable by prescription, such as oxycodone, hydrocodone, codeine, morphine, and fentanyl, as well as the illegal drug heroin. Upon ingestion, opioids attach to specific proteins called "opioid receptors," which are distributed throughout the body's central nervous system. When activated, these receptors produce analgesic effects and a sense of euphoria in the user.[1]

21. Opioid users develop a tolerance for the drug. As a 2002 paper describes, "[r]epeated exposure to escalating dosages of opioids alters the brain so that it functions more or less normally when the drugs are present and abnormally when they are not."[2] As time goes by, the opioid user needs more and more opioids to feel "normal," produce comparable levels of pleasure,, and to avoid negative symptoms of withdrawal.[3] However, opioid tolerance may begin to develop after a single dose, particularly with regard to the drug's analgesic and euphoric effects.[4]

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[1] *See* Hasan Pathan & John Williams, *Basic Opioid Pharmacology: An Update*, 6 British J. of Pain 11 (2012).

[2] Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 Sci. & Practice Perspectives 14 (July 2002), *available at* http://bit.ly/2DwcTP1.

[3] *Id*. at 15.

[4] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconception and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016); Jessica Wapner, *CDC Study Finds*

22. This vicious cycle, if not checked, results in addiction: "[o]pioids not only directly activate these brain analgesia and reward regions but also concurrently mediate a learned association between receipt of the drug and the physiological and perceptual effects of the drug—a type of Pavlovian conditioning."[5]

23. Thus, opioid use can readily lead to addiction, misuse, dependence, and abuse. And indeed, it has, with the United States' present opioid epidemic being described by some as "the worst drug crisis in American history."[6] For instance, opioid users may also seek to increase their dosage and maintain their euphoric high by snorting or injecting crushed opiate pills and tampering with extended release tablets.[7] They may also transition to cheaper black market opioids such as heroin—according to the National Institute on Drug Abuse, nearly 80 percent of heroin users report misusing prescription opioids before turning to the cheaper, more-powerful drug.[8] The CDC has also noted that addiction to prescription pain medication is the strongest risk

Opioid Dependency Begins Within a Few Days of Initial Use, Newsweek (Mar. 22, 2017), http://www.newsweek.com/cdc-opiate-addiction-572498.

[5] Nora D. Volkow & A. Thomas McLellan, *supra* note 4.

[6] Nora D. Volkow & A. Thomas McLellan, *supra* note 4; Dan Nolan, *How Bad is the Opioid Epidemic?*, Frontline (Feb. 23, 2016), https://www.pbs.org/wgbh/frontline/article/how-bad-is-the-opioid-epidemic/.

[7] Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016);

[8] Nat. Institute on Drug Abuse, *DrugFacts: What is Heroin?* (last revised Jun. 2018), https://www.drugabuse.gov/publications/drugfacts/heroin#ref; *see also* Pradip K. Muhuri, et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Ctr. for Behavior Health Stats. & Quality Data Rev. (Aug. 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

factor leading to heroin addiction, with those addicted to opioid pills being 40 times more likely to become addicted to heroin.[9]

24. The use and abuse of opioids can also have devastating secondary medical consequences. For example, there is "a significant association between opiate use" and various forms of cancer, including cancer of the "bladder, kidney, oral cavity, esophagus, and other pharynx cancers."[10]

25. In 2015, over two million people in the United States had a substance abuse disorder involving prescription opioids.[11]

26. Because of their potent analgesic and euphoric effects, along with its high potential for addiction (particularly when used for extended periods), prescription opioids like oxycodone and hydrocodone have been classified as Schedule II narcotics under the federal Controlled Substances Act. 21 C.F.R. § 1308.12. Schedule II is a category that includes substances like methamphetamine and cocaine.

27. Opioids have a demonstrated, scientifically-proven use in treating "breakthrough" cancer-related pain, and have been prescribed for years to treat such pain. "Breakthrough" pain refers to pain that "breaks through" the relief provided by an existing regimen of pain relievers.

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[9] *See* Ctrs. for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015); *see also* Wilson M. Compton, *supra* note 7.

[10] *See* Hamideh Rashidan, et al., *An Ecological Study of the Association Between Opiate Use and Incidence of Cancers*, 8 Addict Health 252 (2016).

[11] Am. Soc. Of Addiction Med., *Opioid Addiction Facts and Figures* 1 (last visited Oct. 25, 2018), https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

28. While opioids have also been prescribed for years to treat breakthrough chronic non-cancer pain, the efficacy of long-term opioid use for such ailments has never been reliably demonstrated through sufficient evidence or high-quality scientific research.[12] There have been few randomized controlled trials regarding opioid efficacy for non-cancer pain and even fewer double-blind studies.

29. Critically, while the short-term use of opioids for "breakthrough" pain have become part of the medical consensus, no studies have found that long-term opioid use is beneficial.[13]

30. As a 2006 Canadian meta-analysis found, a majority of studies of opioid use related to chronic non-cancer pain were funded by the pharmaceutical industry itself, and *none* had found concrete evidence of opioids improving functioning over non-opioid analgesics. Instead, the Canadian analysis concluded, "for functional outcomes the other analgesics were significantly more effective than were opioids."[14]

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[12] Hasan Pathan & John Williams, *supra* note 1, at 15. Opioids' use as a predictable, effective source of short-term pain relief has even been called into question. A 2004 meta-analysis of literature published between 1996 and 2003 on opioids and pain relief found that, in patients taking doses for periods of up to eight weeks, opioid use only reduced reported pain by 2 points on a "1 to 10" pain scale, or a 30 percent reduction of pain compared to patients taking placebos. For some conditions, opioids provided either an insignificant reduction in pain over a placebo or failed to provide at least a 30% reduction in pain. Thus, Dr. Andrea Rubinstein, M.D. concludes that even short-term opioid efficacy is a "far cry from the 'complete relief' expected by many patients." *See* Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Mag. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747; *see also* Eija Kalso, et al., *Opioids in Chronic Non-Cancer Pain: Systemic Review of Efficacy and Safety*, 21 Pain 372 (2004).

[13] *See* Andrea Rubinstein, *supra* note 12.

[14] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 Canadian Med. Ass'n J. 1589 (2006).

31. A 2006 Danish study had even blunter findings, stating that **"it is remarkable that opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life, and improved functional capacity."**[15]

32. The FDA essentially reiterated this point in a 2013 letter, stating that it was unaware "of [any] adequate and well-controlled studies of opioid use longer than 12-weeks."[16]

33. The Centers for Disease Control ("CDC") has come to the same conclusion. In 2016 the CDC published a Guideline for Prescribing Opioids for Chronic Pain following a "systematic review of the best available evidence" by a panel of experts free from conflicts of interest. The CDC found no useful long-term studies of opioids' effectiveness for treating chronic pain or improving patients' day-to-day functioning or quality of life.[17]

34. One thing is certain about opioids, however: "prescribing opioids for their analgesic effects will typically require increasingly higher doses in order to maintain the initial level of analgesia—up to 10 times the original dose."[18]

35. Despite this, "[o]pioids are … frequently prescribed within the [medical] community, where codeine, oxycodone and buprenorphine are commonly used for chronic pain"

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[15] Jorgen Eriksen, et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, 125 Pain 172, 176–77 (2006) (emphasis added).

[16] Letter from Janet Woodcock, M.D., Director, Ctr. For Drug Evaluation & Research to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), *available at* http://bit.ly/2F430US.

[17] Deborah Dowell, et al, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[18] Nora D. Volkow & A. Thomas McLellan, *supra* note 4; *see also* Chante Buntin-Mushock, et al., *Age-Dependent Opioid Escalation in Chronic Pain Patients*, 100 Anesthesia & Analgesia 1740 (2005) (noting observation of "[r]apid opioid dose escalation" in daily opioid therapy patients in a study assessing the relationship between age and opioid tolerance).

treatment.[19] How opioids came to be widely prescribed for long-term use—without scientific proof that they even worked for that purpose—is a key focus of this lawsuit.

36. The risks of opioid treatment for chronic pain are high, as patients who receive increasing doses of opioids to treat chronic non-cancer pain have as much as a nine times higher chance of overdose.[20] Indeed, studies on opioid use have demonstrated a correlation between high opioid dosage and poor physical function, as well as worsened overall general health.[21] Another study confirmed that patients using opioids for chronic pain scored lower than non-opioid users across multiple criteria such as physical function, social function, vitality, and pain.[22]

37. Opioid use also delays injury recovery and increases the risk of permanent disability. In a study of Workers Compensation claims for lower back pain, increasing a patient's opioid dosage was found to correlate with an increasing risk of disability compared to non-opioid users.[23] Another study showed that prescribing opioids within six weeks of an injury actually *doubled* the risks of disability one year later.[24] Likewise, studies on opioid use prior to back

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[19] Hasan Pathan & John Williams, *supra* note 1, at 15.

[20] Kate M. Dunn, et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152 Ann. Intern. Med. 85 (2010).

[21] Kathryn Sullivan Dillie, et al., *Quality of Life Associated With Daily Opioid Therapy in a Primary Care Chronic Pain Sample*, 21 J. of the Am. Bd. Of Fam. Med. 108 (2008).

[22] Andrea Rubinstein, *supra* note 12.

[23] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at* https://www.colorado.gov/pacific/sites/default/files/Psycholigical%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf (citing Barbara S. Webster, et al., *Relationship Between Early Opioid Prescribing for Acute Occupation Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery, and Late Opioid Use*, 32 Spine 2127 (Sept. 2007)).

[24] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at*

surgery show poorer outcomes for patients including increased pain, decreased function, and increased depression.[25]

38. Worst of all, opioid use can ultimately lead to death by overdose—and does, with a frequency that has led the medical profession, the federal government, the media, and even (in some cases) Defendants to describe the current state of affairs as an "epidemic" or "crisis."[26]

B. The National Opioid Epidemic.

39. Today, opioids are the main driver of drug overdose deaths in the United States.[27] From 1999 to 2014, more than 165,000 Americans died from an overdose related to opioid use.[28] In 2015 alone, 35,000 Americans died from opioid-related deaths.[29]

40. This rise in overdose deaths has been a major contributor to the decline in U.S.

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https://www.colorado.gov/pacific/sites/default/files/Psycholigical%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf (citing Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: the Disability Risk Identtification Study Cohort*, 33 Spine 199 (2008)).

[25] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016), *available at* https://www.colorado.gov/pacific/sites/default/files/Psycholigical%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf (citing Sheyan J. Armaghani, et al., *Preoperative Opioid Use as a Predictor of Adverse Postoperative Self-Reported Outcomes in Patients Undergoing Spine Surgery*, 96 J. Bone & Joint Surgery (American) e89 (2014)).

[26] *See, e.g.*, Proclamation No. 9499, 81 Fed. Reg. 65,172 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Awareness Week."); Ctrs. for Disease Control and Prevention, *supra* note 9; Elizabeth Cohen, *US Surgeon General Sends Warning Letter To All Doctors On Opioid Epidemic*, CNN (Aug. 25, 2016), https://www.cnn.com/2016/08/25/health/us-surgeon-general-letter-doctors-opioid-use/index.html.

[27] See Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Opioid Overdose, (December 16, 2016), https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[28] Deborah Dowell, et al, *supra* note 17.

[29] *Overdose Death Rates | National Institute on Drug Abuse (NIDA),* https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last visited Nov. 7, 2018).

life expectancy, which fell in 2015 and 2016—the first such multi-year drop since the early 1960s.[30]

41. Prescription opioids' increasingly wide use has been the key feature of these problems. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a five-milligram dose of hydrocodone every four hours for one month.[31]

42. In 2011, the CDC declared prescription painkiller overdoses to be at epidemic levels, noting that over 40 people die per day from overdoses of narcotic pain relievers like Vicodin, OxyContin, and Opana, and that nearly 5,500 people begin misusing prescription painkillers every day.[32]

43. Today, the number of opioid prescriptions issued annually in the United States is roughly equal to the size of its entire adult population.[33] And the explosive growth in painkiller prescriptions has been concurrent with a rise in heroin deaths across the country, with the CDC reporting a tripling of heroin overdoses between 2010 and 2014 alone.[34]

44. The societal costs of prescription opioid abuse are enormous. Across the country, local governments are struggling with a pernicious, ever-expanding epidemic that "affects public

[30] Rob Stein, *Life Expectancy Drops Again As Opioid Deaths Surge in U.S.*, NPR (Dec. 21, 2017), https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s.

[31] Katherine M. Keyes, et al., *Trends In Opioid Analgesic Abuse And Mortality In The United States*, 372 N. Eng. J. Med. 241 (2015).

[32] *See* Press Release, Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses At Epidemic Levels* (Nov. 1, 2011).

[33] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016)

[34] *See* Rose A. Rudd, et al., *Increases In Drug And Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

health as well as social and economic welfare," according to the National Institute on Drug Abuse.[35] Estimates of the total financial impact of this burden—including the costs of providing health care, lost worker productivity, and criminal justice-related costs—reach as high as $500 *billion*.[36]

45. As the crisis continues to take a toll on communities around the country, the manufacturers and distributors of prescription opioids have extracted (and continue to make) billions of dollars in revenue from the American public off the sale of these drugs. Meanwhile, local governments and patients like Plaintiff Kevin Schwartz have been forced to shoulder an ever-growing share of the opioid epidemic's burdens.

46. This state of affairs could have been avoided, but for the conduct of Defendants and their opioid manufacturer cohorts. Defendants have engaged in a pattern and practice of wrongful, intentional, and unlawful conduct to push prescription opioids onto the public and into communities, in pursuit of record profits from this product line. Defendants did so despite knowing of the reasonably foreseeable consequences to Plaintiff: addiction, as one of many addictions arising from a prescription opioid epidemic of a tragic, enormous magnitude.

II. Purdue and Other Opioid Manufacturers Engaged In A Years'-Long Campaign To Increase Opioid Sales By Misrepresenting Their Risks And Benefits.

47. The use of opioids for managing long-term, non-cancer pain is now understood to be based on "unsound science and blatant misinformation … and dangerous assumptions that

[35] Nat'l Inst. On Drug Abuse, *Opioid Overdose Crisis* (last visited Nov. 7, 2018), *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

[36] White House Council of Economic Advisers, *The Underestimated Cost of the Opioid Crisis*, Table 3 (Nov. 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf .

opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[37]

48. This was commonly understood even in the early 1990s, when opioids were commonly used to treat acute pain. As Dr. Russell Portenoy, a former pain specialist at New York's Memorial Sloan Kettering Cancer Center (and publicly an ardent promoter of opioid usage), put it in a 1994 book:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain….

In contrast with this statement, the prior year Dr. Portenoy—who received funding for his work from Defendant Purdue—had told the *New York Times* that opioids were a "gift from nature," ought to be destigmatized, and that concerns about addiction and abuse were a mere "medical myth" aimed at propagating hysterical "opiophobia" in the medical profession.[38]

49. In a 2012 interview with the *Wall Street Journal,* following two decades of promoting opioids as an effective tool for chronic non-cancer pain relief, Dr. Portenoy admitted that his advocacy had been in error: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? … I guess I did."[39]

50. But Dr. Portenoy was far from alone in spreading this "misinformation." Defendants and other opioid manufacturers orchestrated, participated in, and benefitted from a

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[37] Standiford Helm II, et al., *Opioid Epidemic in the United States*, 15 Pain Physician 9 (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmed/22786464?report.

[38] Elisabeth Rosenthal, *Patients in Pain Find Relief, Not Addiction, in Narcotics*, N.Y. Times (Mar. 28, 1993), http://www.nytimes.com/1993/03/28/us/patients-in-pain-find-relief-not-addiction-in-narcotics.html?pagewanted=all.

[39] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall. St. J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

major campaign to shift the public's and medical profession's perception of prescription opioids by disseminating misinformation about the efficacy and safety of long-term opioid use, while downplaying its severe risks. These manufacturers included, but were not limited to, Defendants Purdue and Endo, as well as the companies Cephalon, Inc., Allergan PLC, Mallinckrodt PLC, and Janssen Pharmaceuticals, Inc. (collectively with Purdue and Endo and hereafter, "Opioid Manufacturers," unless otherwise specified).

51. Opioid Manufacturers have conducted marketing schemes designed to persuade doctors and patients that opioids can and should be prescribed for treating chronic non-cancer pain. This has resulted in opioids being used to treat for a far broader group patients than would have otherwise been possible, both in Plaintiffs' community and nationwide.

52. In connection with this scheme, Opioid Manufacturers spent millions of dollars on promotional activities and materials that falsely denied or trivialized the risks of opioids, while overstating their benefits in treating chronic non-cancer pain.

53. Opioid Manufacturers have made false and misleading claims, often contrary to the contents of their drugs' labeling. Among other things, Opioid Manufacturers have:

- Downplayed the risk of addiction;
- Created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing;
- Advocated doctors should treat the signs of addiction with more opioids;
- Downplayed the difficulty of managing opioid dependence and withdrawal;
- Denied the risks of taking increasingly higher doses of prescription opioids over time; and
- Exaggerated the efficacy of 'abuse-deterrent' opioid formulations to prevent abuse and addiction.

54. Opioid Manufacturers have repeatedly, broadly, and falsely touted the benefits of long-term opioid use, including their alleged ability to improve functioning and quality of

life for chronic non-cancer pain patients, despite—as described above—a lack of any valid basis in scientifically reliable evidence.

55. These messages were disseminated by Opioid Manufacturers directly through sales representatives, through speaker groups led by physicians specifically recruited by the Opioid Manufacturers, through unbranded, misleading marketing materials, and through industry-funded Front Groups (with generic names like the American Pain Society).[40]

56. To say that Opioid Manufacturers' efforts have been successful (by its measure) would be a gross understatement. Since 1999, the amount of opioids prescribed in the United States has nearly quadrupled. Opioids are now the most prescribed class of drugs in the country, with U.S. sales generating tens of billions of dollars in revenue for the Opioid Manufacturers.

57. In a 2016 letter to physicians across the country, then-Surgeon General Vivek H. Murthy expressly connected this success in selling opioids to "heavy marketing of opioids to doctors … [m]any of [whom] were even taught—incorrectly—that opioids are not

[40] *See, e.g.*, Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain; Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, Associated Press (Sept. 19, 2016), https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7; Maggie Fox, *Many Doctors Get Goodies from Opioid Makers*, NBC (Aug. 10, 2017) https://www.nbcnews.com/storyline/americas-heroin-epidemic/many-doctors-get-goodies-opioid-makers-n791281 (noting that "one out of every 12 U.S. doctors gets money … or something else of value from companies that make opioid drugs"); Lynette Reid & Matthew Herder, *The Speakers' Bureau System: A Form of Peer Selling*, 7 Open Med e31 (2013); Jeffrey J. Meffert, *Key Opinion Leaders: Where They Come From and How That Affects the Drugs You Prescribe*, 22 Dermatologic Therapy 262 (2009); IMAP, *Speakers' Bureaus: Best Practices for Academic Medical Centers* (Oct. 10, 2013), http://bit.ly/2E1bhdd ("Speakers' bureaus may lead to the dissemination of false or biased information" due in part to the "compensation provided for these engagements.")

addictive when prescribed for legitimate pain."[41]

58. But Opioid Manufacturers' success has come at tremendous costs for communities and patients across the country, including Plaintiffs and their Ohio community. Nonetheless, Opioid Manufacturers continued on in a campaign of deception, knowing that they were causing an epidemic and the widespread harms attendant to it.

A. Opioid Manufacturers Push Junk Science and Misleading Claims.

59. Opioid Manufacturers' marketing efforts proceeded along two tracks, serving related purposes.

60. First, Opioid Manufacturers worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks. Second, individual Opioid Manufacturers worked through their own staffs of sales representatives, physician speakers (whom those representatives recruited), and advertisements in medical journals to claim their share of that broadened market for opioid products.

61. Opioid Manufacturers directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

62. Because they reside in one of the most populous areas of Ohio, Plaintiffs' community is an important target of Opioid Manufacturers' efforts, based on the area's population density, resultant sales efficiency, and demographics. Opioid Manufacturers employed the same marketing plans and strategies described herein in and around Plaintiffs' community as they did across Ohio, and nationwide.

[41] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), *available at* http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf.

63. As described herein, Opioid Manufacturers' misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic non-cancer pain were part and parcel of Opioid Manufacturers' deceptive marketing campaigns in Plaintiffs' community and nationwide.

1. Opioid Manufacturers' use of deceptive marketing

64. Opioid Manufacturers engaged in widespread advertising campaigns touting the benefits of their drugs.

65. Opioid Manufacturers published print advertisements in a broad array of medical journals, ranging from those aimed at specialists (such as the *Journal of Pain* and *Clinical Journal of Pain*) to journals with wider medical audiences (such as the *Journal of the American Medical Association*). Though Defendants' budgets for such advertisements peaked in 2011—when they collectively spent over $14 million on medical journal advertising—they had regularly engaged in such conduct since at least 2001.

66. Many of these branded advertisements deceptively portrayed the benefits and risks of opioid therapy for treating chronic pain. For example, a 2005 Purdue advertisement running in the *Journal of Pain* stated that one of its opioid products was an "around-the-clock analgesic ... for an extended period of time." The advertisement featured a man and boy fishing and stated that "There Can Be Life With Relief." This depiction falsely implied that Purdue's opioids could provide effective long-term pain relief and functional improvement—such claims are not substantiated by the medical literature, both then and now.

2. Opioid Manufacturers deceptively promoted opioids through sales representatives and self-recruited physician speakers.

67. Each Opioid Manufacturer promoted the use of opioids for chronic pain through "detailers"— sales representatives who visited individual physicians and their staff in their

offices—and small group speaker programs. By establishing close relationships with doctors, Opioid Manufacturers' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings allowing them to differentiate their opioids and to address individual doctors' concerns about prescribing opioids for chronic non-cancer pain.

68. Representatives were trained on techniques to build these relationships.

69. Opioid Manufacturers have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe.[42]

70. Opioid Manufacturers developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Opioid Manufacturers purchased and closely analyzed prescription sales data from IMS Health that allowed them to track, precisely, the rates of initial prescribing and renewal by individual doctors. This, in turn, allowed them to target, tailor, and monitor the impact of their appeals to prescribe more opioids for chronic non-cancer pain treatment.

[42] *See, e.g.,* Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33 Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in *on*-label prescription of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and tripling of annual sales calls).

71. Opioid Manufacturers in particular relied upon "influence mapping," using decile rankings (or similar breakdowns) to identify high-volume prescribers for whom detailing could have the greatest sales impact.

72. Opioid Manufacturers also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

73. Opioid Manufacturers' sales representatives have visited hundreds of thousands of doctors, including numerous visits to prescribers in Plaintiffs' community. These visits were used to spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain.

74. Each Opioid Manufacturer carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs in particular and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages, and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aides reviewed, approved, and supplied by the company.

75. Sales representatives' adherence to their corporate training is typically included in their work agreements. Departing from their company's approved messaging could and did lead to severe consequences, including termination of employment.

76. In addition to making sales calls, Opioid Manufacturers' detailers also identified doctors to serve, for payment, on Opioid Manufacturers' speakers' bureaus and to attend programs with speakers and meals paid for by Opioid Manufacturers.

77. Opioid Manufacturers almost always selected physicians to be speakers who are "product loyalists," since one question they will invariably be asked is whether they prescribe the drug themselves. Such invitations are lucrative to the physicians selected for these bureaus.

78. These speaker programs and associated speaker training served three purposes: they provided an incentive to doctors to prescribe, or increase their prescriptions of, opioids; the provided a forum in which to further market prescription opioids to the speaker him or herself; and provide an opportunity to market to the speaker's peers.

79. Opioid Manufacturers grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Opioid Manufacturers also track the prescribing of event attendees.

80. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them by Opioid Manufacturers. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Opioid Manufacturers.

81. Although these speaker events are more expensive to host, and typically have lower attendance than Continuing Medical Education ("CME") courses, they are subject to less professional scrutiny. Thus, they afford Opioid Manufacturers greater freedom in the messages they can convey to doctors.

82. Opioid Manufacturers have devoted massive resources to these direct sales contacts with prescribers. In 2000, Opioid Manufacturers were spending about $50 million on detailing branded opioids to physicians nationwide; by 2014, that number had jumped to $168

million. This 2014 figure includes, upon information and belief, $108 million spent by Defendant Purdue and $10 million spent by Defendant Endo.

3. Opioid Manufacturers use Front Groups, doctors, and unbranded marketing to push bogus opioid claims—and their products.

83. In addition to their direct marketing efforts, Opioid Manufacturers used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Opioid Manufacturer executed these strategies through a network of third-party Key Opinion Leaders ("KOLs") and Front Groups, with which they acted in concert by funding, assisting, encouraging, and directing their efforts, while at the same time exercising substantial control over the content of these third parties' messages.

84. As with their other marketing strategies, Opioid Manufacturers' unbranded marketing created and relied upon an appearance of independence and credibility that was undeserved but central to its effectiveness. By using unbranded communications, drug companies sidestepped the extensive regulatory framework governing branded communications.

85. Opioid Manufacturers disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Opioid Manufacturers' marketing plans, which specifically contemplated their involvement because they seemed independent (and therefore outside of FDA oversight.) Through unbranded materials, Opioid Manufacturers presented information and instructions concerning opioids that were contrary to, or at best inconsistent with, information and instructions listed on Opioid Manufacturers' branded marketing materials and drug labels—including as to Purdue and Endo. This was done with Opioid Manufacturers' knowledge of the true risks, benefits, and advantages of opioids.

86. Opioid Manufacturers did so knowing, and in reliance on the fact that, such unbranded materials are typically not submitted to nor reviewed by the FDA.

87. Even where such unbranded messages were channeled through third-party vehicles, Opioid Manufacturers adopted these messages as their own by citing to, editing, approving, and/or distributing such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

88. Moreover, Opioid Manufacturers took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Opioid Manufacturers were consistently aware of their content. By funding, directing, editing, and distributing these materials, Opioid Manufacturers exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

89. The third-party publications Opioid Manufacturers assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to them. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

a. Opioid Manufacturers developed KOLs.

90. Opioid Manufacturers cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Opioid Manufacturers solely because they favored the aggressive treatment of chronic pain with opioids.[43]

[43] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators

91. Opioid Manufacturers' support helped these doctors become respected industry experts. In return, these doctors repaid Opioid Manufacturers by touting the benefits of opioids to treat chronic pain.

92. Pro-opioid doctors have been at the hub of Opioid Manufacturers' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, given speeches, and led CMEs supportive of opioid therapy for chronic non-cancer pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain (while knowing of the lack of evidence to support the practice), as well as on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

93. Opioid Manufacturers were able to exert control over each of these modalities through their KOLs. In return, the KOLs' association with Opioid Manufacturers provided them not only money, but prestige, recognition, research funding, and avenues to publish their research. This positioned the KOLs—and by association, Opioid Manufacturers—to exert even more influence in the medical community.

94. Opioid Manufacturers cited and promoted favorable studies or articles by these KOLs. In contrast, Opioid Manufacturers did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by Opioid Manufacturers (and specifically Purdue), the aforementioned Dr. Portenoy,

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that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

95. Some KOLs have even gone on to become direct employees and executives of Opioid Manufacturers, like Dr. David Haddox, a Vice President of Risk Management for Purdue, or Dr. Bradley Galer, a former Chief Medical Officer for Endo.

96. Opioid Manufacturers provided substantial opportunities for KOLs to participate in research on topics Opioid Manufacturers suggested or chose, with the predictable effect of ensuring many favorable studies appeared in the academic literature. As described by KOL Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Portenoy regularly agreed to do so.

97. Opioid Manufacturers also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. From 2000 on, the Opioid Manufacturer Cephalon, Inc., for instance, paid doctors more than $4.5 million for such programs relating to its opioids.

98. Opioid Manufacturers kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers, discussed above. The KOLs knew or deliberately ignored the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Opioid Manufacturers, all the while causing harm to prescribers and patients in Plaintiffs' community as a result.

99. As indicated above, Dr. Russell Portenoy was a favorite Opioid Manufacturer KOL. Dr. Portenoy received research support, consulting fees, and honoraria from Defendant Purdue (among others), and was a paid consultant to Purdue.

100. Dr. Portenoy was instrumental in opening the door to the use of opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain—first through their widely-distributed 1997 guidelines, and again through the guidelines' 2009 version. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy group almost entirely funded by Opioid Manufacturers.

101. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations.

102. Recently, Dr. Portenoy has admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures regularly cited, among other misleading claims, the Purdue-created falsehood that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks.

103. Dr. Portenoy has also conceded that "[d]ata about the effectiveness of opioids does not exist."[44]

104. Dr. Lynn Webster was another favorite KOL. Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a

[44] Thomas Catan & Evan Perez, *supra* note 39.

front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published special advertising supplements for Endo touting its opioid product Opana ER.

105. Dr. Webster was the author of numerous CMEs sponsored by Endo and Purdue. At the same time he did so, Dr. Webster received significant funding from Opioid Manufacturers (including nearly $2 million from Opioid Manufacturer Cephalon, Inc. alone).

106. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than twenty of Dr. Webster's former patients at the Lifetree Clinic died from opioid overdoses.

107. Dr. Webster was a leading proponent of the concept of "pseudoaddiction," a scientifically unproven—yet frequently touted—notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate between the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases … should be the clinician's first response." Defendant Endo distributed this book to doctors.

108. Years later, Dr. Webster said that "[pseudoaddiction] obviously became … an excuse to give patients more medication."[45]

109. Dr. Scott Fishman was another favored KOL, and was the author of the deceptive 2007 guide *Responsible Opioid Prescribing*, discussed below, which was paid for, in part by Purdue and Endo.

[45] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee J. Sentinel (Feb. 19, 2012), *available at* https://www.medpagetoday.com/neurology/painmanagement/31254.

110. Fishman's ties to the opioid drug industry are legion. Fishman was a past president of the AAPM, as well as a board member of the APF, both discussed below and referenced above. He has participated in numerous opioid-friendly continuing medical education courses for which he has received compensation by one or more Opioid Manufacturers, and helped to lobby against anti-opioid legislation.

111. Fishman himself has acknowledged his failure to disclose all of his potential conflicts of interests in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures In A Letter On Reducing Opioid Abuse and Diversion."[46]

112. There are numerous other KOLs that Opioid Manufacturers have developed and utilized over the years, including Dr. Perry G. Fine and Dr. David Haddox. These KOLs' stories largely mirror the stories of Portenoy, Webster, and Fishman, depicting doctors eager to do Opioid Manufacturers' bidding by promoting prescription opioids for unsupported uses, in order to increase their profiles, fund their research, and, as a result, grow the market for prescription opioids.

b. Opioid Manufacturers knowingly pushed bogus "research."

113. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Opioid Manufacturers led everyone to believe that they already had.

114. Opioid Manufacturers created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and third-party payors.

[46] Scott M. Fishman, *Incomplete Financial Disclosures In A Letter On Reducing Opioid Abuse And Diversion*, 30 J. Am. Med. Ass'n 1445 (2011).

115. This information, masquerading as scientific literature, was actually marketing material, focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

116. To accomplish this, Opioid Manufacturers—sometimes through third-party consultants or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Opioid Manufacturers coordinated the timing and publication of manuscripts, abstracts, posters, oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs.

117. The plans for these materials did not originate in the departments within Opioid Manufacturers that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients. Rather, they came from their marketing departments, and from marketing and public relations consultants.

118. Opioid Manufacturers often relied on "data on file" publications or presentation posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Opioid Manufacturers to publish, in nationally circulated journals, studies supportive of their drugs.

119. Opioid Manufacturers also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study.

120. One notable example is the Opioid Manufacturers' aggressive promotion of a 1980 letter that appeared in the well-respected New England Journal of Medicine: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. 123 (1980) ("Porter-Jick Letter"). The letter is cited over 800 times in cases collected on Google Scholar. It

also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[47] Upon information and belief, each Opioid Manufacturer (including Purdue and Endo) has repeatedly referenced the Porter-Jick Letter in their marketing materials—branded and/or unbranded—since its publication in 1980.

121. Opioid Manufacturers and those acting on their behalf fail to reveal that this "article" is actually a letter to the editor, not a study. The Porter-Jick Letter describes a review of the charts of hospitalized patients who had received opioids. (Because the review was conducted in 1980, standards of care from the time almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.) The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction—though there is no indication that caregivers were instructed to assess or document signs of addiction.

122. None of these serious limitations was disclosed when Opioid Manufacturers or those acting on their behalf cited the Porter-Jick Letter, often as the sole scientific support for the proposition that opioids are rarely addictive even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.[48]

123. As researchers reviewing the Porter-Jick Letter's use by opioid promoters concluded, this "five-sentence letter published in … 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy [and] this citation pattern

[47] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Plaintiff's community.

[48] *Painful Words: How A 1980 Letter Fueled The Opioid Epidemic*, Associated Press (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[49]

124. Opioid Manufacturers worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Opioid Manufacturers' studies and articles often targeted articles that contradicted Opioid Manufacturers' claims or raised concerns about chronic opioid therapy. In order to do so, Opioid Manufacturers—often with the help of third-party consultants—targeted a broad range of media to get their message out, including articles, letters to the editor, commentaries, case-study reports, and newsletters.

125. These strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief, distorting prescribing patterns as a result.

c. Opioid Manufacturers push favorable treatment guidelines.

126. Treatment guidelines were particularly important to securing acceptance for chronic pain opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors (frequent targets of Opioid Manufacturers) who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments.

127. Opioid Manufacturers, on a number of occasions, promoted (and helped pay for) the publication of treatment guidelines that supported a more widespread use of their prescription opioid products than contemporary science and medicine justified.

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[49] German Lopez, *A 5-Sentence Letter Helped Trigger America's Deadliest Drug Overdose Crisis Ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study.

128. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States, including the State Medical Board of Ohio. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

129. The FSMB has financed opioid- and pain-specific programs through grants from Defendants and other Opioid Manufacturers.

130. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies." The FSMB guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines fail to mention risks of overdose, and discuss addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

131. A 2004 iteration of the FSMB Guidelines and a 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also made these claims.

132. These guidelines were posted online and were available to and intended to reach physicians in Plaintiffs' community that were able to prescribe opioids for their patients.

133. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Endo and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Purdue, for bulk sales and distribution to sales representatives (for later distribution to prescribing doctors).

134. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards across the country (and through the boards, to practicing doctors), including

Ohio's medical board and doctors in Plaintiffs' community. The FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website described the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

135. Opioid Manufacturers also relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe they would be disciplined if their patients became addicted to opioids, were taught that they would instead be punished if they failed to prescribe opioids to their patients with pain.

136. Indeed, the FSMB actually issued a report calling on medical boards to punish doctors who inadequately treat pain.[50]

137. Upon information and belief, from 2001 to 2012 the FSMB received at least $820,000 in payments from Purdue and at least $370,000 in payments from Endo. Upon information and belief, this included at least $50,000 from Purdue and $40,000 from Endo to specifically fund the production of *Responsible Opioid Prescribing*.

138. In a 2012 letter to the Senate Finance Committee—which was then investigating the abuse of prescription opioids—the FSMB stated that *Responsible Opioid Prescribing* had been distributed in all 50 states and the District of Columbia.[51]

139. Similarly flawed guidelines were published by the AAPM and APS, each of which received substantial funding from Opioid Manufacturers, including Defendants. These

[50] Thomas Catan & Evan Perez, *supra* note 39.

[51] Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley (June 8, 2012), *available at* http://bit.ly/2tnvN65.

organizations also issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.

140. The co-author of the AAPM-APS statement, KOL Dr. David Haddox, was at the time a paid speaker for Purdue.[52] KOL Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011, and was available to and intended to reach physicians in Plaintiffs' community that were responsible for deciding whether to prescribe opioids to their patients.

141. AAPM and APS issued their own guidelines in 2009 ("AAPM-APS Guidelines") and continued to recommend the use of opioids to treat chronic non-cancer pain. Fully two-thirds of the panel members—14 of 21 members—who drafted the AAPM-APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Purdue and Endo, among other Opioid Manufacturers.

142. The AAPM-APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by Opioid Manufacturers' contributions.

143. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies. The AAPM-APS Guidelines committee clearly failed to meet this standard.

[52] Patrick Radden Keefe, *supra* note 40.

144. These AAPM-APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians in Plaintiffs' community (including physicians visited and relied upon by Plaintiff) but also the body of scientific evidence on opioids.

145. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

146. Finally, the American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines").

147. The 2002 AGS Guidelines included the following statements: "consensus statements from major professional pain organizations endorse [the use of opioids] in appropriate situations (e.g., [AAPM] and [APS]), "[r]eluctance to prescribe these drugs has probably been over-infuenced by political and social pressures to control illicit drug use," "the incidence of addictive behavior among patients taking opioid drugs for medical indications appears to be very low," "studies increasingly suggest that [opioid] tolerance ... is slow to develop," and that "in most cases, it makes sense [for patients in pain] to progress from non-opioid analgesics, such as acetaminophen, to ... opioids."[53]

148. The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of

[53] *See generally The Management of Persistent Pain in Older Persons*, 50 J. Am. Geriatrics Soc'y 205 (2002).

evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[54]

149. These recommendations, which continue to appear on AGS's website, are not supported by reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

150. AGS contracted with Endo and Purdue (among other Opioid Manufacturers) to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. Purdue and Endo were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to Purdue and Endo beginning July 15, 2009.

151. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[55] Five of 10 of the experts on the guidelines panel disclosed financial ties to Opioid Manufacturers, including serving as paid speakers and consultants, presenting classes sponsored by them, receiving grants from them, and investing in their stock.

d. Opioid Manufacturers relied on Continuing Medical Education (CME) programs to disseminate misleading information.

152. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure.

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[54] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009).

[55] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel (May 30, 2012).

153. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are delivered by doctors who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

154. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Opioid Manufacturers aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Opioid Manufacturers' deceptions (delivered via KOLs).

155. In all, Opioid Manufacturers sponsored CMEs that were delivered thousands of times—including numerous CMEs attended by physicians in Plaintiffs' community—promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

156. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs. It urges

that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[56]

157. Dozens of CMEs that were available to and attended or reviewed by doctors in Plaintiffs' community during the relevant time period did not live up to the AMA's standards.

158. The influence of Opioid Manufacturers' funding on the content of these CMEs is unmistakable. One study by a Georgetown University Medical Center professor compared the messages retained by those who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Participants who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. Those that read the non-industry-funded CME mentioned the risks of death and addiction much more frequently. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[57]

159. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, Opioid Manufacturers could expect messages to be favorable to them. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy.

e. Opioid Manufacturers make frequent use of Front Groups.

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[56] Opinion 9.2.7, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education.

[57] Letter from Senator Claire McCaskill to James A. Schoeneck, President and Chief Executive Officer of Depomed, at 2–3 (Mar. 28, 2017) *available at* https://www.hsgac.senate.gov/imo/media/doc/McCaskill%20Opioid%20Letters.pdf.

160. Opioid Manufacturers, including Purdue and Endo, entered into arrangements with numerous organizations to promote opioids, including many of those identified above. These organizations depend upon Defendants and other Opioid Manufacturers for significant funding and, in some cases, for their survival.

161. These Front Groups were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Opioid Manufacturers' marketing in other ways—for example, responding to negative articles, lobbying against regulatory changes that would constrain opioid prescribing, and criticizing non-industry-created guidelines for opioid prescribing (such as those published by the CDC). They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Opioid Manufacturers, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain.

162. Opioid Manufacturers funded these Front Groups to disseminate supportive messages from seemingly neutral, credible third parties. These efforts were successful.

163. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, AAPM, FSMB, the American Chronic Pain Association

("ACPA"), and the American Society of Pain Educators ("ASPE"). **See Figure 1.**

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	**$1,265,566.81**
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	**$1,199,409.95**
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	**$304,605.00**
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	**$168,500.00**
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	**$417,140.00**
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	**$11,785.00**
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	**$25,000.00**
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	**$962,724.52**
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	**$30,000.00**
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	**$323,212.85**
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	**$163,095.00**
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	**$562,500.00**
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	**$2,922,800.00**
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	**$500,000.00**
	$4,153,554.33	**$465,152.85**	**$1,071,116.95**	**$3,146,265.00**	**$20,250.00**	**$8,856,339.13**

Figure 1.[58]

164. For years, the most prominent of Opioid Manufacturers' Front Groups was APF, which received tens of millions of dollars in funding from Opioid Manufacturers from 1997 to 2012, when it closed its doors. Purdue and Endo were among some of APF's largest funders.

[58] U.S. Senate Homeland Security & Governmental Affairs Comm., *Fueling An Epidemic: Exposing The Financial Ties Between Opioid Manufacturers And Third Party Advocacy Groups*, at 4 (Feb. 12, 2018), *available at* https://www.hsgac.senate.gov/download/fueling-an-epidemic-exposing-the-financial-ties-between-opioid-manufacturers-and-third-party-advocacy-groups.

Indeed, in 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources, including industry grants for specific projects. By 2011, APF was entirely dependent on incoming grants from Purdue, Endo, and other Opioid Manufacturers.

165. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign—through radio, television and the Internet—to educate patients about their "right" to pain treatment, namely through opioids. All of the programs and materials were available nationally and intended to reach patients in Plaintiffs' community.

166. APF held itself out as an independent patient advocacy organization. It often purported to engage in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Opioid Manufacturers' promotional activities, including for Purdue's opioid toolkit *Partners Against Pain*. Indeed, as early as 2001, Purdue told APF that the basis of a grant it was giving the organization was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

167. In practice, APF operated in extremely close collaboration with Opioid Manufacturers. On several occasions, representatives of the Opioid Manufacturers (often at informal meetings at Front Group conferences) suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

168. One example of APF's activities stands out from the rest. *Exit Wounds* is a 2009

publication sponsored by Purdue, and distributed by APF with grants from Endo and other Opioid Manufacturers. It is written as the personal narrative of a military veteran, and describes opioids as "underused" and the "gold standard of pain medications" while failing to disclose the risk of addiction, overdose, or injury.

169. *Exit Wounds* notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." It also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." (As laid out above, the FSMB itself received support from Opioid Manufacturers during the time it created and published these guidelines.)

170. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose that opioids may cause fatal interactions with benzodiazepines, which are taken by a significant number of veterans. It is not the unbiased narrative of a returning war veteran: it is pure marketing, sponsored by Purdue, Endo, and other Opioid Manufacturers.

171. *Exit Wounds*' deceptive nature is obvious in comparison to guidance on opioids published by the U.S. Veterans Administration in 2010 and 2011. That guidance, *Taking Opioids Responsibly*, describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. It also offers the list of side effects from opioids, including decreased hormones (referring to testosterone), nausea, sleep apnea, addiction, immune system changes, birth defects and death—none of which are disclosed in *Exit Wounds*.

172. The U.S. Senate Finance Committee began looking into APF in May 2012 to

determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Opioid Manufacturers stopped funding it.

173. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

174. The second most prominent of Opioid Manufacturers' Front Groups, AAPM, was similarly conflicted. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers.

175. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California (or other resort locations). AAPM described the annual event as an "exclusive venue" for offering education programs to doctors.

176. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Purdue and Endo were members of the council, along with other Opioid Manufacturers, and presented deceptive programs to doctors who attended this annual event.

177. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs such as Dr. Perry Fine, and the aforementioned KOLs Portenoy and Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated at the AAPM's 21st annual meeting that he

would place the organization "at the forefront" of teaching that "the risks of addiction are … small and can be managed."[59]

178. AAPM's staff understood that they and their industry funders were engaged in a common task: promoting prescription opioids at any cost. Opioid Manufacturers were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

179. One other vehicle for Opioid Manufacturers' collective efforts bears mentioning here: the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goal of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

180. PCF is primarily composed of representatives from Opioid Manufacturers (including Purdue and Endo) and distributors; industry-friendly professional organizations (*e.g.*, AAPM, APS, and the American Society of Pain Educators); industry-friendly patient advocacy groups (*e.g.*, APF); like-minded organizations (*e.g.*, FSMB); and doctors and nurses favorable to these entities' messaging on prescription opioids.

181. PCF developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids, which the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients. This was critical because

[59] Paula Moyer, *The Current State of Pain Management*, MedScape (2005), https://www.medscape.org/viewarticle/500829. Note that the disclaimer at the bottom of the articles states that "[t]his program was supported by an independent educational grant from Cephalon," an Opioid Manufacturer. *Id.*

a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would deflate Opioid Manufacturers' marketing efforts.

182. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." As such, Opioid Manufacturers worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

183. Overall, the PCF spent $140 million to lobby state and national legislatures on an array of Opioid Manufacturer-friendly issues, including issues directly related to the manufacturing, distribution, sale, and/or prescription of opioids.

184. Thus, like cigarette manufacturers before them, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Opioid Manufacturers worked with each other and with, and through, the Front Groups and KOLs they funded and directed, to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic non-cancer pain. In speeches, lectures, pamphlets, and books, Opioid Manufacturers deliberately fed misinformation about prescription opioids to the public and medical profession, which were deceived into believing the false and misleading claims.

B. Additional Examples of Purdue's Conduct.

185. Purdue, perhaps more than any other Opioid Manufacturer, exemplifies the industry's deceptive approach to marketing prescription opioids since the late 1990s.

186. Purdue, which is privately held by the Sackler family, manufactures, and then markets, sells, and distributes Schedule II narcotics nationwide, including but not limited to:

- **OxyContin (oxycodone hydrochloride extended release).** An opioid agonist meant to treat pain severe enough to require daily, around-the-clock, long-term treatment. It is not indicated as an "as-needed" analgesic. First approved by the FDA in December 1995.
- **MS Contin (morphine sulfate extended release)**. A controlled-release tablet form of morphine sulfate, indicated for severe pain management and not intended for as-needed use. First approved by the FDA in May 1987 as an opioid pain medicine allowing for dosing every twelve hours.
- **Dilaudid (hydromorphone hydrochloride)**. Injectable and oral opioid analgesic that is eight times more potent than morphine. A related medication, **Dilaudid-HP**, is a higher-potency and more concentrated formulation of the drug intended for moderate-to-severe pain relief in opioid-tolerant patients.
- **Hysingla ER (hydrocodone bitrate**). A brand name, extended-release form of hydrocodone bitrate indicated for the management of severe pain.
- **Targiniq ER.** A brand name, extended release combination of oxycodone hydrochloride and naloxone hydrochloride. First approved by the FDA on July 23, 2013.[60]

187. Purdue has also manufactured, marketed, sold, and distributed generic forms of oxycodone nationwide.

188. Before Purdue launched its flagship opioid brand OxyContin in 1996, opioids were typically used to treat severe short-term pain, except for in terminally ill patients. This was because, as indicated above, the medical community was aware of both the risks of opioids and the relative ineffectiveness of their long-term use in treating most forms of chronic pain. The conventional wisdom was that opioids would appear effective in the short term, but prove ineffective over time with increasingly negative, dire side effects (including addiction).

189. So when Purdue launched OxyContin, it sought to broaden its use to treating most or all forms of chronic pain—including back pain, arthritis, and headaches. This plan had the benefit of producing a more sustained revenue stream for Purdue, in light of the greater frequency of those maladies. But the company hit a snag: doctors were too worried about the risk

[60] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to elicit a certain response. An "antagonist" medication, conversely, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response.

of patients becoming addicts (or worse) to give them prescription opioids for these illnesses.

190. Purdue engaged in in-person marketing to doctors in Ohio and operated speakers bureau programs that included and targeted Ohio prescribers. Purdue employed hundreds of sales representatives dedicated to pushing opioid products full-time. Like the other Opioid Manufacturers' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers. Indeed, internal documents from Endo indicate that pharmaceutical sales representatives employed by Purdue (and Endo) discussed the AAPM/APS Guidelines with doctors during individual sales visits. (As discussed above, these Guidelines incorrectly posit that the risk of addiction is manageable for patients regardless of past abuse histories.)

191. But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

192. Purdue's sales culture, including in Plaintiffs' community, was one that mandated opioids be aggressively sold, embracing a sell-at-any-cost notion. Aggressive quotas were put in place of opioids, including OxyContin, at all dosage levels, as well as Hysingla products. The highest dosage for OxyContin was even referred to by Purdue sales representatives as "hillbilly heroin."

193. When sales representatives failed to meet their quotas, they were placed on performance employment plans and/or terminated. When they were successful, they were richly rewarded with extravagant bonuses and prizes.

194. As such, Purdue set out to—and did—convince doctors that patients with legitimate pain who took opioids and remained under a doctor's supervision would not become addicted, and that the overall risk of addiction extremely low. The methods and means by which

Purdue accomplished this are multi-faceted.

1. Purdue's deceptive direct marketing

a. Purdue falsely marketed extended-release OxyContin as superior to immediate-release opioids and downplayed the risks of addiction.

195. Purdue launched OxyContin 20 years ago with a powerful, bold claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[61] Purdue told doctors in its OxyContin press release that a single tablet would provide "smooth and sustained pain control all day and all night."

196. Purdue knew, however, that these claims were misleading because, for many patients, the pain relief lasted for as little as eight hours, which led to end-of-dose failure and withdrawal symptoms and prompted doctors to prescribe or patients to take higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

197. For example, a "Conversion and Titration Guide" submitted to the FDA and distributed to physicians by Purdue, prominently referred to "Q12h OxyContin Tablets," meaning that each tablet is intended to "offer your patient every-twelve-hour dosing."

198. Purdue advertisements that ran in 2005 and 2006 issues of the Journal of Pain depict a sample prescription for OxyContin with "Q12h" handwritten. Another advertisement Purdue ran in 2005 in the Journal of Pain touted OxyContin's "Q12h dosing convenience" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 Clinical Journal of Pain.

199. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

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[61] Harriet Ryan, et al., *"You Want A Description Of Hell?", OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

200. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described to be a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function (and there was substantial evidence to the contrary).

201. In large part because of these promises, the nationwide marketing campaign to promote it, and Purdue's repeated assurances that opioids were both effective and largely non-addictive, OxyContin became America's bestselling painkiller.

202. Purdue's nationwide marketing claims were highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off earlier than 12 hours, as Purdue's own studies showed, but it is highly addictive.

203. A Los Angeles Times investigation of OxyContin reviewed thousands of pages of confidential Purdue documents, court records, emails, memoranda, meeting minutes and sales reports, spanning three decades from the conception of OxyContin in the mid-1980s to 2011. It also reviewed sworn testimony by Purdue executives, sales representatives, and other employees. The investigation found that:

- Purdue knew for decades that it was falsely promising 12-hour pain relief from OxyContin;
- Even before going to market, Purdue's clinical trials showed many patients were not getting 12 hours of relief;
- Purdue was repeatedly confronted with complaints from doctors, researchers, and reports from its own sales representatives and independent research about the substance of the 12-hour relief claim, but broadly ignored these complaints;
- Purdue maintained and mobilized a team of hundreds of sales representatives to "refocus" physicians across the country, on 12-hour dosing, despite a lack of evidence behind it;
- Purdue told doctors to prescribe stronger and stronger doses of OxyContin for patients who continue to complain of pain, and/or become tolerant (even

though this approach created a greater possibility of addiction, overdose, and death); and

- Purdue's motivation behind these acts and omissions was, in large part, to protect and grow its revenue, because without the 12-hour claim OxyContin would have little advantage over less expensive painkillers on the market.[62]

204. Reporting by the New York Times confirmed many of these claims, including that "internal Purdue documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue knowingly and falsely promised a long-acting, extended release formulation of OxyContin as safer and "less prone to such problems."[63]

205. Purdue also pushed these false and misleading claims, and engaged in such false and deceptive practices, as it pertained to the generic oxycodone and other opioid products it manufactured, particularly those marketed or described as provided 12-hour relief.

206. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk of addiction and abuse, Purdue also promoted the use of prescription opioids—including both OxyContin and generic oxycodone—for use in non-cancer patients and non-acute pain patients, who now make up 86 percent of the total prescription opioid market.[64] Rather than target physicians prescribing opioids for understood, scientifically-supported uses, Purdue heavily promoted OxyContin and generic oxycodone for unsupported uses and targeted doctors such as general practitioners, who often had little training in treating

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[62] Harriet Ryan, et al., *Full Coverage: OxyContin Investigation*, L.A. Times (2016), http://www.latimes.com/projects/la-me-oxycontin-full-coverage/.

[63] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.

[64] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down As Senators Launch Investigation Of Prescription Narcotics*, ProPublica (May 8, 2012), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

serious pain or recognizing the signs of drug abuse in patients.[65]

207. Purdue sales representatives accomplished this, in part, by plying these physicians with coupons redeemable for a 7- to 30-day supply of OxyContin—a Schedule II narcotic that cannot be prescribed for more than one month at a time—and an accompanying promise that the drug was safe. It "trained its sales rep[s] to carry the message that the risk of addiction was 'less than one percent,'" and systematically minimized the risk of addiction in the use of opioids for treating chronic non-cancer pain.[66]

208. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue knew that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"—downplaying much more prevalent signs of addiction associated with OxyContin use, such as asking for early refills, and making it seem that addiction only occurs when opioids are taken illicitly.

209. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of pseudoaddiction had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in Providing Relief, Preventing Abuse did Purdue disclose the lack of scientific evidence justifying the concept of pseudoaddiction, nor that it was coined by a Purdue vice president.

210. Even as late as 2015, Purdue representatives were telling physicians that OxyContin was "addiction resistant" and utilized "abuse-deterrent technology." This was untrue.

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[65] Barry Meier, *supra* note 53.

[66] Art Van Zee, *supra* note 42.

211. Purdue tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from IMS Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. Purdue also could identify physicians writing large numbers of prescriptions, and particular for its high-dose 80 mg pills—potentially signs of diversion, drug dealing, and/or abuse.

212. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from its sales representatives, and, in some cases, its own investigations. For example, since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were over 1,800 doctors in Region Zero—but Purdue had reported fewer than one-tenth of them to authorities.

213. According to the Los Angeles Times investigation, a "former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[67]

d. Purdue used unbranded marketing to downplay addiction risks.

214. Purdue also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

215. Consistent with Purdue's efforts to portray opioid treatment as "essential" for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an "inadequate understanding" that leads to "inadequate pain control," *In the Face of Pain* criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

[67] Harriet Ryan, et al., *More Than 1 Million OxyContin Pills Ended Up In The Hands Of Criminals and Addicts: What The Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/ projects/la-me-oxycontin-part2/.

216. Purdue also used its unbranded website *Partners Against Pain* to promote the deceptive messages regarding risk of addiction that were delivered by its sales representatives. On this website, Purdue posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005. Purdue distributed a hard-copy version of this pamphlet thereafter. *Clinical Issues in Opioid Prescribing* claimed that "illicit drug use and deception" were not indicia of addiction, but rather indications that a patient's pain was undertreated. The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

2. Purdue's deceptive third-party statements

217. Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials; it also engaged third parties (including Front Group APF) to spread the false message of their prescription opioids' safety and efficacy.

a. Purdue's Control of APF

218. Purdue exercised considerable control over APF, which published and disseminated in many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in detail below.

219. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling $1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel

participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF

220. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives.

221. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). Based on interviews conducted and documents reviewed by the City, PCF was and continues to be run not by APF, but by Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Burt Rosen was able to tell PCF "what to do and how to do it," and also asserted that this allowed him to run APF. According to this employee, to Rosen's thinking, "PCF was APF, which was Purdue." The group meets regularly in-person and via teleconference and shares information through an email listserv.

222. Purdue's control over APF also shaped and was demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—Purdue chief among them.

223. In all, Purdue exerted substantial influence and control over APF's activities from the time of its founding in the 1990s until it shut down in 2012.

(i) A Policymaker's Guide

224. Purdue provided significant funding to and was involved with APF in creating and disseminating *A Policymaker's Guide to Understanding Pain & Its Management*. *Policymaker's Guide* misrepresented that that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

225. Specifically, *Policymaker's Guide* claimed that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."[68]

226. *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and that "less than 1% of children treated with opioids become addicted."

227. Moreover, *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as pseudoaddiction, which, according to the guide, "describes patient behaviors that may occur when pain is undertreated." Like *Partners Against Pain*, *Policymaker's Guide* noted that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." The similarity between these messages regarding pseudo-addiction highlights the common, concerted effort behind Purdue's deceptive statements.

228. *Policymaker's Guide* further misrepresented the safety of increasing doses of

[68] Andrea D. Furlan et al., *supra* note 14.

opioids and deceptively minimized the risk of withdrawal. For example, *Policymaker's Guide* claimed that "[s]ymptoms of physical dependence" on opioids in long-term patients "can often be ameliorated by gradually decreasing the dose of medication during discontinuation" while omitting the significant hardship that often accompanies cessation of use. Similarly, *Policymaker's Guide* taught that even indefinite dose escalations are "sometimes necessary" to reach adequate levels of pain relief, but it completely omitted the safety risks associated with increased doses.

229. Purdue provided substantial assistance toward the creation and dissemination of *Policymaker's Guide*, which APF ultimately disseminated on behalf of Defendants, including Purdue. Purdue provided $26,000 in grant money to fund the development and dissemination of its content. Purdue kept abreast of the content of the guide as it was being developed, and, based on the periodic reports APF provided to Purdue regarding its progress on Policymaker's Guide, had editorial input into its contents.

230. Policymaker's Guide was posted online, and was available to and intended to reach Ohio prescribers and consumers.

(*ii*) *Treatment Options: A Guide for People Living with Pain*

231. Purdue's partnership with APF did not end with *Policymaker's Guide*. Purdue also substantially assisted APF by sponsoring and exerting control over the creation of *Treatment Options: A Guide for People Living with Pain*.

232. *Treatment Options* is rife with misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresented that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

233. Further, as outlined above, *Treatment Options* claimed that addiction is rare and, when it does occur, involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, which paints a narrow and misleading portrait of opioid addiction. As described above, there is no scientific evidence corroborating that statement, and such statements are, in fact, false because available data demonstrate that patients on chronic opioid therapy are less likely to participate in life activities like work.

234. *Treatment Options* also promoted the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* noted that NSAIDs can be dangerous at high doses and inflated the number of deaths associated with NSAID use, and distinguished opioids as having less risk. According to *Treatment Options*, NSAIDs were different from opioids because opioids had "no ceiling dose," which was beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warned that the risks associated with NSAID use increased if NSAIDs were "taken for more than a period of months," but deceptively omitted any similar warning about the risks associated with the long-term use of opioids.

235. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. Treatment Options was also posted online. It was available to and intended to reach Ohio prescribers and patients.

(*iii*) *Exit Wounds*

236. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

237. Purdue provided APF with substantial assistance in distributing *Exit Wounds* in

Ohio and throughout the nation by providing grant money and other resources.

b. Purdue's work with other third-party Front Groups and KOLs

238. Purdue also provided other third-party front groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

(i) FSMB—Responsible Opioid Prescribing

239. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by "Medical Writer X."

240. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally, and its message was available to and intended to reach prescribers in Plaintiff's network.

(*ii*) *AGS—Pharmacological Management of Persistent Pain in Older Persons*

241. Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed above, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" when the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation)."

242. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and "the appearance of conflict." Accordingly, AGS endeavored to

eliminate "the root cause of that flack" by turning down commercial support to produce the 2009 Guidelines. Having determined that its veneer of independence would be tarnished if it accepted drug company money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies instead for funding to distribute the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's "strategy that we will take commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming." AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

243. AGS sought and obtained grants from Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons.* As a result, the publication was distributed nationally, and its message was available to and was intended to reach prescribers in Plaintiffs' community. Indeed, as mentioned, internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Purdue discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.[69]

(*iii*) *CME's*

244. Purdue sponsored a 2012 CME program taught by Steven Stanos, a Chicago-based KOL, called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations

[69] As described above, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants.

in the United States.

245. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation likewise deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach prescribers nationwide.

246. Purdue also sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse. Path of the Patient is devoted entirely to treating chronic pain with opioids. Although the program purports to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, but only discusses treatment of chronic pain with opioids.

247. In a role-play in Path of the Patient, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach prescribers nationwide.

248. Purdue also sponsored a CME titled Overview of Management Options and issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which was still available for CME credit as of June 2018). The CME was edited by KOL Russel Portenoy, among others. It deceptively instructed physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In fact, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online intended to reach prescribers nationwide, including in Plaintiffs' community.

(iv) Purdue's misleading science.

249. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins in Chicago, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.[70] Purdue had these articles placed in headache-specific journals, where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar.

250. Five years later, Purdue also funded a study of opioids in diabetic neuropathy patients, which was published in 2003.

251. Notwithstanding that Purdue-funded studies, testing Purdue's own drugs, had

[70] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache, 19 Headache Q. 305 (1999).

previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that opioids were not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times.[71]

252. While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

C. Additional Examples of Endo's Conduct.

253. Endo manufactures, and then markets, sells, and distributes the following Schedule II prescription opioids nationwide, including in Plaintiff's community:

- **Opana** (oxymorphone hydrochloride). An opioid agonist approved by the FDA in 2006. An extended release version, **Opana ER**, was also approved in 2006.
- **Percodan** (oxycodone hydrochloride and asprin). Endo's branded oxycodone tablet. Approved by the FDA in 1950, first marketed in 2004.
- **Percocet** (oxycodone and acetaminophen). Another branded oxycodone tablet. First approved by the FDA in 1999, first marketed in 2006.
- **Oxycodone, Oxymorphone, Hydromorphone, Hydrocodone**. Endo manufactures and sells generic versions of these prescription opioids.

254. According to Endo's annual reports, sales of prescription opioids regularly at least hundreds of millions of dollars in annual revenue for the company.

1. Endo's deceptive marketing.

255. Endo's promotion of opioids relied heavily on in-person marketing, including to Ohio prescribers. Endo had an aggressive detailing program, with its sales representatives making nearly 72,000 visits to prescribers nationwide to detail opioids in the first quarter of 2010 alone. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to

[71] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

promote opioids, including its generics, through its sales force. Upon information and belief, Endo spent millions on such activities over the ten years prior to this period.

256. Endo's sales representatives, like those of the other Opioid Manufacturers, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

257. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain.

258. Endo knew that its marketing reached physicians —repeatedly—because it tracked their exposure.

259. Endo also knew that its marketing messages were successfully imparted to the physicians it targeted. For example, Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse," the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage.

260. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescriptions for Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month.

261. Endo also leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers programs around the country, including

Ohio. These programs were attended by sales representatives, which reveal their true purpose as marketing, rather than educational, events.

262. Endo trained its sales force and recruited speakers for its speakers bureau presentations to make a number of misrepresentations to physicians nationwide, including to physicians in Ohio. Endo's sales representatives were trained to represent to these prescribers that opioids would help patients regain function they had lost to chronic pain; that Endo opioids had a lower potential for abuse because they were "designed to be crush resistant," even though the "clinical significance of INTAC Technology or its impact on abuse/misuse has not been established" for Endo's opioid products; and that drug seeking behavior was a sign of undertreated pain rather than addiction.

a. Endo deceptively minimized the risks of addiction associated with chronic opioid therapy.

263. Endo's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. For example, Endo circulated an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which implied to persons providing care to chronic pain patients that addiction was not a substantial concern by stating that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." This program was downloadable from Endo's website and accessible to prescribers nationwide.

264. Further, until April 2012, Endo's website for Opana, www.opana.com, contained the following representation: "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

265. The Office of the Attorney General of New York has also disclosed that training materials provided by Endo to sales representatives stated: "Symptoms of withdrawal do not indicate addiction." This representation not only defied common sense, but was completely inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association.

266. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from the phony malady "pseudoaddiction," discussed elsewhere in this complaint. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

b. Endo deceptively implied that chronic opioid therapy would improve patients' ability to function.

267. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long-term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to, and does not, improve patients' functioning, and in fact, is often accompanies by serious side effects that degrade functioning. Endo's own internal documents acknowledged that claims about improved quality of life were unsubstantiated "off label claims."

268. For example, in a 2007 Sales Tool intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic lower back pain. Per the Sales Tool, Endo's opioid products would make it more likely that Bill could return to work and support his family—this was false and misleading.

269. For another example, one can look to an Endo sales training video dated March 8, 2012, which Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Ohio.

270. Claims of improved functionality were central to Endo's marketing efforts for years, including, upon information and belief, during the time that Plaintiff was addicted to prescription opioids.

271. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, it distributed in Ohio and elsewhere a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed "a massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

2. Endo's deceptive third-party statements

272. Like the other Defendants, Endo provided substantial funding to purportedly neutral medical organizations to produce false and misleading materials concerning the risks and benefits of prescription opioids. Prior to, but in contemplation of, the 2006 launch of Opana ER, Endo spent millions of dollars supporting organizations whose primary purpose was to spread

misinformation about prescription opioids.

273. As a part of this, Endo developed a "Public Stakeholder Strategy," which included identifying "tier one" advocates to assist in promoting the approval and acceptance of Endo's extended release opioid products. Endo also enlisted the support of organizations favorable to opioids from a sales perspective, and that had engaged in, or had the potential to advocate for, favorable public policy. Endo sought to develop its relationships with these organizations through its funding—by 2008, Endo was spending $1 million per year to do so, including by attending meetings of pro-opioid Front Groups like AAPM.

a. APF.

274. One of the Front Groups with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed, including through its National Initiative on Pain Control ("NIPC"). Endo was one of the APF's biggest financial supporters, and Endo provided more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo spent $1.1 million on the NIPC program in 2008 alone, funding earmarked, in part, for the creation of CME materials that were intended to be used over and over again.

275. Nowhere was Endo's relationship with APF closer than with its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services, but that company was determined to be a "commercial interest" by the ACCME and could no longer serve as a sponsor. In response, Endo reached out to APF.

276. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in distribution of NIPC and APF materials,

which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

277. Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in and access to NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, Painknowledge.com. Endo not only knew how many people viewed NIPC's content, but what their backgrounds were (*e.g.*, primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

278. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution.

279. In short, NIPC was a key piece of Endo's marketing strategy.

280. Endo's influence over APF's activities was so pervasive that APF President Will Rowe even reached out to Defendants—including Endo—rather than his own staff to identify potential authors to answer unfavorable articles about prescription opioids. Personnel from Defendants and other Opioid Manufacturers worked with Rowe to formulate APF's responses. The response suggested by Defendants would be the one that APF ultimately published.

(*i*) *Misleading Medical Education*

281. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" and sponsored by Endo. These newsletters were edited by KOL Dr. Perry Fine and also listed several industry-backed KOLs, including Dr. Webster, as

individual authors.

282. Endo documents made clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity.

283. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's does by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

284. NIPC webcast these CMEs from its own website, where they were available to and were intended to reach prescribers nationwide, including those in Plaintiff's network.

(*ii*) *Painknowledge.org*

285. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC's website, *Painknowledge.org*, which touted itself as "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[72] Endo tracked visitors to *Painknowledge.org* and used *Painknowledge.org* to broadcast notifications about additional

[72] PainKnowledge, *AboutPainKnowledge.org* (last visited Nov. 8, 2018), http://web.archive.org/web/20130513010647/http://www.painknowledge.org/aboutpaink.aspx.

NIPC programming that Endo helped to create.

286. True to APF's word, *Painknowledge.org* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function.

287. *Painknowledge.org* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted." *Painknowledge.org* did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain. Among other featured content, *Painknowledge.org* included a flyer titled "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

288. Endo was the sole funder of *Painknowledge.org*, and it continued to provide that funding despite being aware of the website's misleading contents.

(*iii*) *Exit Wounds*

289. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that, as described above, also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain.

290. *Exit Wounds* was drafted by "Medical Writer X." Medical Writer X was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors. This, in combination with Endo's exercised dominance over APF and the projects it

undertook in an effort to promote the use of opioids to treat chronic pain, gave Endo considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

291. Along with other Opioid Manufacturer, including Purdue, Endo provided grants to the APF to distribute *Exit Wounds*, as discussed above.

b. Other Front Groups: FSMB, AAPM, and AGS

292. In addition to its involvement with APF, Endo worked closely with other third-party front groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo in some instances used its sales force to directly distribute certain publications by these front groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R. § 1.3(a).

293. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Medical Writer X."

294. Endo spent $246,620 to help FSMB distribute *Responsible Opioid Prescribing.* Endo approved this book for distribution by its sales force. Based on the uniform and nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including physicians in Plaintiffs' community.

295. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a $44,850 donation. As described above, these guidelines misleadingly claimed that "the

risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," since the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)" when in reality, opioid therapy was an appropriate treatment only for a subset of those patients, as Endo's FDA-mandated labels recognized.

296. AGS's grant request to Endo made explicit reference to the CME Endo was funding. Endo thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether to invest in it. After having sponsored it, Endo's internal documents indicate that Endo's pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

297. Endo also worked with AAPM, which it viewed internally as "Industry Friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

298. One such talk written by Endo in 2009, titled *The Role of Opana ER in the Management of Chronic Pain*, includes a slide titled Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements as outlined above, while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

299. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo discussed treatment guidelines with doctors during individual

sales visits.

c. KOLs and other misleading science

300. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

301. Endo sponsored articles, authored by an Endo consultant and Endo employees, which argued that the metabolic pathways utilized by its opioid products made it less likely than other opioid products to result in drug interactions in elderly low back and osteoarthritis pain patients.

302. Endo distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

303. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers in Plaintiffs' community.

304. Endo also sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*.[73] The article stated that:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain**.** The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

[73] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain, Pain Med. News*, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf.

305. The article included a case study that focused on the danger of extended use of nonsteroidal anti-inflammatory drugs (NSAIDs) (a class of pain relief drugs that includes ibuprofen, among others). The case study reported that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that *"use of opioids may be effective in the management of chronic pain."*

306. In 2008, Endo also provided an "educational grant" to *PainEDU.org*, which produced a document titled "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

307. Endo also made thousands of payments to physicians nationwide, including to physicians in Plaintiffs' community, for activities including participating on speakers' bureaus, providing consulting services, and other services.

d. Deceptive statements in Plaintiffs' community.

308. Endo also directed the dissemination of the misstatements described above to patients and prescribers in Plaintiffs' community in and around Toledo, Ohio. Endo accomplished this through its sales force, speakers bureaus, CMEs, and its painknowledge.com website. This conduct occurred, upon information and belief, both during and after the time Plaintiff Kevin Schwartz was addicted to prescription opioids.

309. For example, Endo hired a New York-based KOL to deliver a CME titled *Managing Persistent Pain in the Older Patient* on April 27, 2010. This CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event (and other NIPC programs) was sent to "all healthcare professionals" in APF's database.

310. Endo knew that the harms from its deceptive conduct would be felt in and around Toledo, Ohio. It especially saw workers' compensation programs as a lucrative opportunity, and promoted the use of opioids for chronic pain arising from work-related injuries, such as chronic lower back pain. Endo developed plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees." By 2007, Endo had in place a plan to reach 5,000 workers' compensation carriers to ensure that its opioids would be covered.

III. Defendants' Conduct Directly Led to Plaintiff's Opioid Addiction.

311. Defendants repeatedly chose to maximize their profits at the expense of the public, allowing for knowing or negligent improper sales of massive quantities of opioids in and around Toledo, across Ohio, and around the United States.

312. Opioids have had an acute impact in Ohio. In 2007, unintentional drug poisoning became the leading cause of injury-death in Ohio, surpassing motor vehicle accidents for the first time in history. By 2012, the total number of opioid doses prescribed had soared to 793 million—enough to supply every man, woman, and child in the state with 68 pills each.[74] In

[74] Ohio Prescription Drug Abuse Task Force, Final Report – October 1, 2010; Ohio Opiate Action Team, Fighting Prescription Drug Abuse, Rx Prescribing Guidelines; Ohio Automated RX Reporting System, 2016 Annual Report.

2016 alone, 2.3 million Ohio patients—roughly 20% of the state's population—were prescribed an opioid drug.

313. At the local level, this crisis has manifested itself in rural, urban, and suburban communities alike across Ohio, including among many residents of Plaintiffs' home city, Toledo, and its surrounding area in Lucas County. Indeed, since 2004 the unintentional drug overdose death rate in Lucas County has skyrocketed by more than 700%.[75] The highest concentration of overdoses in Lucas County has been within Toledo, which makes up half of the county's population.

314. More than 1 million Ohio citizens now suffer from chronic pain, which takes an enormous toll on their health, lives and families.[76] These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Ohio patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgement and subjected them to enormous costs and suffering.

315. One of these patients was Plaintiff Kevin Schwartz, who for many years worked as a truck driver. Schwartz has lived in Toledo, Ohio with his wife, Plaintiff Stephanie Schwartz, since 2000.

316. In January of 2001, after exiting the cab of his truck one winter evening, Schwartz slipped and fell on an icy parking lot. Schwartz landed on his lower back and buttocks.

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[75] Ohio Dep't of Health, *2016 Ohio Drug Overdose Data: General Findings*, at 9 (2017), *available at* https://bit.ly/2ReEpmr.

[76] *Id.*

317. Although Schwartz felt fine immediately following the incident, the next morning he could not get out of bed due to the pain in his back. His wife immediately took him to see a doctor in Toledo—Dr. Glenn Rothaas—who prescribed him Ibuprofen.

318. On February 15, 2001, Dr. Rothaas began prescribing Schwartz 20 milligram tablets of 12-hour extended release oxycodone hydrochloride. Based on the 10-digit National Drug Code number associated with the prescription, the oxycodone was manufactured by Purdue. Later that year, Schwartz came under the care of a different physician—Dr. Ernest Bode—who not only continued to prescribe him oxycodone, but increased his dosage significantly.

319. Upon information and belief, Kevin Schwartz's doctors prescribed him opioids in reliance on representations made by Opioid Manufacturers, including Defendants—both on their own and/or through third-party KOLs and Front Groups—that opioid products could be used in large doses to treat chronic non-cancer pain, including chronic back pain like Kevin Schwartz's.

320. Over the following years, and in reliance on the advice of his doctors, Schwartz was consistently prescribed oxycodone to treat chronic pain stemming from his back injury. Overall, the advice these doctors gave was misinformed, as a direct and proximate consequence of Purdue's and Endo's deceptive campaigns to increase sales of their opioid products in Toledo, in Ohio, and across the country. Schwartz's doctors assured him that opioids were a safe, reasonable treatment option for the chronic pain he experienced following his fall.

321. At times, Schwartz was given multiple prescriptions, and took opioids several times per day. The size of the individual prescriptions varied over time, reaching as high as 80 milligram doses of oxycodone.

322. During the time of his addiction, beginning in February 2001, Schwartz had 109 prescriptions filled for oxycodone ranging from 10 milligrams to 80 milligrams per dose in size, and further varied by delivery method (*e.g.* extended release versus instant release). Of these, 91 prescriptions were comprised of Purdue-manufactured oxycodone and 14 were comprised of Endo-manufactured oxycodone, according to the National Drug Codes associated with each prescription.

323. At first, the opioids eased the pain of Kevin Schwartz's injuries. Schwartz felt as though he could barely move at times, overwhelmed by the drugs' strength. Still, based on the reassurances he'd received from his doctors, he believed continuing to take the drugs was the best course of action.

324. Although his pain improved, over the next few months opioids became something other than just a helpful tool for Schwartz—they were an outright necessity. Schwartz would spend days at a time nearly motionless, generally only getting out of his living room chair to eat, sleep, and deal with the emerging, severe physical symptoms of long-term opioid use and addiction (including nausea and bowel problems).

325. Throughout the next five years, Schwartz lived a life defined by addiction, to the detriment of both him and his marriage. Stephanie Schwartz was almost entirely deprived of her husband's love, companionship, and consortium. Her husband had become a shell of his former self. Kevin had become nonresponsive, sluggish, dazed, and altogether lost in his addiction. Stephanie took care of the housework and home maintenance, while Kevin remained glued to a chair and gained a large amount of weight. He lost most interest in sex and the ability to perform, much less provide her the care and comfort she expected in a supportive marriage.

326. This dynamic continued for four years, until Kevin finally cancelled his prescriptions. His road to leaving opioid addiction behind would be difficult, but ultimately he was able to fight through his severe withdrawal symptoms and stop taking Defendants' opioids altogether.

327. Several years later, Kevin Schwartz was diagnosed with kidney cancer, which imposed years of expensive, time-consuming, painful harm and medical costs on him and his family. This was no accident. "[S]tudies published since 2002 ... suggest that opioids can stimulate the growth and spread of cancer cells,"[77] and there is a "significant association between opiate risk and [the] risk of cancer[]," particularly kidney cancer.[78] These studies point to immunosuppressive and pro-angiogenetic properties of opioids as factors contributing to the growth of cancer cells—as such, heightening the risks of cancer for long-term opioid users.

328. That is precisely what happened to Kevin Schwartz, whose opioid addiction—caused by Defendants—was a major contributing factor to his developing kidney cancer.

329. But for Defendants' egregious conduct, Plaintiff Kevin Schwartz would not have become addicted to prescription opioids and suffered ongoing financial, physical, and emotional harms, including but not limited to drug addiction, nausea, pain, lost income, mental fogginess, headaches, drowsiness, excess money spent on unnecessary opioid prescriptions, and kidney cancer and its associated treatment costs.

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[77] UChicago Medicine, *Evidence Mounts for Link Between Opioids and Cancer Growth*, (Mar. 21, 2012) http://www.uchospitals.edu/news/2012/20120321-opioid.html (noting that "several studies published since 2002 ... suggest that opioids can stimulate the growth and spread of cancer cells.")

[78] Hamideh Rashidan, et al., *An Ecological Study of the Association Between Opiate Use and Incidence of Cancers*, 8 Addict Health 252 (2016); *see also* Ravi K. Grandhi, et al., *Does Opioid Use Cause Angiogenesis and Metastasis?*, 18 Pain Med. 140 (2017); S. Atici, et al., *Liver and Kidney Toxicity in Chronic Use of Opioids: An Experimental Long Term Treatment Model*, 30 J. Biosci. 245 (2005).

330. Similarly, without Defendants' conduct Plaintiff Stephanie Schwartz would not have been deprived of the consortium of her husband.

COUNT I
O.R.C. § 2307.76
(On Behalf of Plaintiff Kevin Schwartz)

331. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

332. Under the Ohio Product Liability Act (OPLA), a product is defective due to an inadequate warning when "at a relevant time after it left the control of its manufacturer," "(a) [t]he manufacturer knew or ... should have known about a risk [] associated with the product and that [] caused harm for which the claimant seeks to recover [] damages," and "(b)[t]he manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover [] damages and in light of the seriousness of that harm." O.R.C. § 2307.76(A)(2).

333. A product can also be defective under the OPLA when "it did not conform ... to a representation made by that manufacturer ... even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation." *Id.* § 2307.77.

334. Defendants, as the manufacturers of dangerous prescription opioids sold throughout Ohio and in Plaintiffs' community, had an obligation to exercise due care in performing their duties, and to provide individuals with accurate, clear warnings about the risk of their prescription opioid products. Defendants also had a duty to warn Plaintiff Kevin Schwartz of the reasonably foreseeable risks and possible benefits of its opioid products, as manufacturers

of dangerous narcotics—and equally, a duty to not actively misrepresent and/or conceal an accurate portrait of those risks and benefits. They utterly failed to live up to these duties.

335. Defendants owed a duty to Plaintiff, in part, because the injury they caused through the deceptive marketing, illegal distribution, and reckless sale of dangerous Schedule II narcotics like prescription opioids was foreseeable to—and indeed, actually foreseen by—Defendants.

336. Reasonably prudent prescription opioid manufacturers would not have misrepresented the risks of prescription opioids, nor overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing. Yet this is precisely what Defendants did by aggressively pushing highly addictive opioids for chronic non-cancer pain and long-term use, despite repeated warnings from law enforcement and federal agencies of the unlawfulness and consequences of such actions (and omissions).

337. Specifically, Defendants consistently employed numerous misrepresentations about opioid treatment that fell well below a reasonable standard of care for entities in their position, including—at minimum—claims that:

- The risk of addiction from chronic opioid therapy is low;
- Such risks can be easily identified and managed;
- Signs of addition constitute "pseudoaddiction" requiring treatment with more opioids;
- Opioid withdrawal can be avoided through tapering;
- Opioid dosages can be increased without additional risk to patients;
- Long-term opioid use improves patient functioning;
- Alternative forms of pain relief medication are riskier than opioids; and
- OxyContin and other forms of extended release oxycodone can provide twelve hours of pain relief.

338. As described herein, Defendants' pushed these bogus claims, and others, both on

their own and through an elaborate array of Front Groups, KOLs, misleading CME programs, and other means. This conduct was willful, dangerous, and in flagrant disregard of the safety of individuals who might be harmed through the use of their opioid products—including Plaintiff Kevin Schwartz.

339. Such misrepresentations (and outright falsehoods) were unsupported by credible scientific research, and represent distinct failures to provide accurate, helpful information to opioid users like Kevin Schwartz about the risk of opioids, as well as representations by Defendants that did not conform to their products' actual qualities. These claims, failure to make accurate, scientifically-supported claims, and failure to provide new and accurate information as it became available (both before and after Plaintiff received opioids) rendered Defendants' opioid products unreasonably dangerous for use.

340. As a result of Defendants' utter failure to take care in their role as prescription opioid manufacturers, Kevin Schwartz has experienced immense harm, becoming a prescription opioid addict for years and developing kidney cancer.

341. Defendants acted with actual malice in taking these actions, as demonstrated by their willful flouting of basic duties and rules governing the marketing and sale of prescription opioids.

342. As such, Defendants are each liable under OPLA. Plaintiff seeks all legal and equitable relief allowed by law, including—but not limited to—injunctive relief requiring Defendants to cease their negligent activity, damages to Plaintiff for the injuries caused by Defendants' negligence, punitive damages, and all other damages and equitable relief allowed by law.

COUNT II
Violation of Ohio Rev. Code § 1345.01, *et seq*.
(On Behalf of Plaintiff Kevin Schwartz)

343. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

344. The Ohio Consumer Sales Practices Act ("OCSPA") provides that "[n]o supplier shall commit an unfair or deceptive act or practice in connection with a consumer transaction. Such an unfair or deceptive act or practice by a supplier violates this section whether it occurs before, during, or after the transaction." Ohio Rev. Code § 1345.02(A). Further, it identifies a number of specific acts as "deceptive," including representations that "the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have." *Id.* §1345.02(B).

345. And § 109:4-3-10 of the Ohio Administrative Code, interpreting the OCSPA, makes it a deceptive act or practice for a supplier in connection with a consumer transaction, to "[m]ake any representations, claims, or assertions of fact, whether orally or in writing, which would cause a reasonable consumer to believe such statements are true, unless, at the time such representations, claims or assertions are made, the supplier possesses or relies upon a reasonable basis in fact such as factual objective, quantifiable, clinical or scientific data or other competent or reliable evidence which substantiates such representations, claims, or assertions of fact."

346. In addition, under Ohio Rev. Stat. § 1345.09(B), the following acts are deemed to be deceptive, pursuant to cases made available for public inspection under § 1345.05(A)(3):

- Making any express or implied statement in connection with the marketing or advertisement of any product that is false, or has the capacity, tendency or effect of deceiving or misleading consumers; or omitting any material information such that the express or implied statement deceives or tends to deceive consumers. *State of Ohio ex re. Rogers v. Airborne Health, Inc.*, Case No. 08-CVH-1217848 (Ct. Cmmn. Pleas, Franklin Cty).

- Making, or causing to be made, any written or oral claim that is false, misleading or deceptive. *State of Ohio ex re. Michael DeWine v. Amgen Inc.*, Case No. 15CV7216 (Ct. Cmmn. Pleas, Franklin Cty).
- Making in a promotional context an express or implied representation, not approved or permitted for use in the labeling or under the FDCA, that a product is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by competent and reliable scientific evidence, whether or not such express or implied representation is made by comparison with another drug or treatment, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, a quotation, or other reference. *Id.*

347. The OCSPA is a "remedial act that courts must liberally construe in favor of the consumer." "It is a remedial act that courts must liberally construe in favor of the consumer." *Williams v. Kia of Bedford,* 2018-Ohio-283, ¶ 22, 104 N.E.3d 924, 930 (internal quotations omitted).

348. Throughout the relevant time period, Defendants, directly through their control of third parties, and/or by aiding and abetting third parties, violated the OCSPA by engaging in unlawful, deceptive, and unfair acts and practices to promote the sale and use of opioids to treat chronic pain. These practices were intended to deceive consumers considering whether or not to purchase prescription opioids, including Plaintiff Kevin Schwartz, as well as the doctors responsible for prescribing them, including Kevin Schwartz's.

349. Defendants directly, as well as indirectly through their control of third parties and/or aiding and abetting third parties, made and disseminated untrue, false, and misleading statements to consumers and prescribers in Plaintiffs' community to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated to area prescribers and consumers to promote the sale and use of opioids for treating chronic non-cancer pain.

350. Defendants also made statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. Defendants and their third-party allies repeatedly failed to disclose, or minimized, material facts about the risks, benefits and uses of opioids. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opinions false or misleading regarding the risks benefits, and uses of opioids—particularly for the treatment of chronic non-cancer pain.

351. These false and misleading statements, and material omissions of fact, included, at minimum:

- Denying that pain patients would become addicted to opioids;
- Omitting that opioids are highly addictive and may result in overdose or death;
- Claiming that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;
- Claiming that the risk of addiction to opioids could be managed and avoided through risk screening tools;
- Claiming that opioid doses can be increased, without disclosing the greater risks of addiction, other injury, or death at higher doses;
- Misleadingly promoting opioids as superior to competing analgesics, such as NSAIDs, including overstating the risks of NSAIDs and citing risks of NSAIDs without disclosing opioids' risks;
- Claiming opioids are an appropriate treatment for chronic pain, and failing to disclose the lack of long-term evidence for their use;
- Claiming chronic opioid therapy would improve patients' function and quality of life;
- Promoting opioids as able to provide lengthier periods of pain relief than was known to occur for many patients;
- Claiming abuse-deterrent opioids reduce addiction and abuse, and are safer than other opioids, and failing to disclose that they do not limit oral abuse, can be defeated with relative ease, and may increase overall abuse; and
- Omitting other material facts that deceived consumers and doctors through Defendants' affirmative representations to them, including other adverse effects of opioid use.

352. Throughout the relevant time period, Defendants and the third parties they controlled made and disseminated such statements and material omissions through an array of marketing channels, including in-person detailing, speaker events, conferences, teleconferences, CMEs, studies, journal articles, supplements, advertisements, brochures, websites, and other patient and doctor education materials.

353. Defendants and the third-parties they controlled knew that these statements were untrue and misleading, or omitted material facts, when they made them, and knew they would likely deceive the public, and Plaintiff, and cause them to purchase prescription opioids they otherwise would not have bought—that was the entire point.

354. Furthermore, the business practices Defendant engaged in during the relevant time period offended public policy, were immoral, unethical, oppressive, and unscrupulous, and have resulted in substantial injury to Plaintiff that is not outweighed by a countervailing benefit to consumers or competition.

355. Among other things, these unfair practices included engaging in false and misleading drug marketing directly and through third parties; promoting the purported advantages of a Schedule II narcotic without substantial, credible scientific evidence to support their claims; failing to present a fair assessment of the risks, benefits, and uses of opioids to consumers; deliberately using unbranded marketing materials to evade FDA oversight and rules prohibiting deceptive marketing; and promoting their opioids for off-label uses. In doing so, Defendants violated the OCSPA by making widespread representations that "the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have." *Id.* §1345.02(B).

356. This conduct offends the public policy of Ohio. But by engaging in the unfair conduct described above, Defendants actively worked to conceal the risk of addition from Ohio patients and prescribers—including Plaintiff and his doctors—in the hopes of selling ever-greater quantities of their products.

357. This conduct was also oppressive to Plaintiff Kevin Schwartz. Plaintiff put his trust in physicians to appropriately convey and balance the risks and benefits of various treatment options for their employees and residents of their communities. Physicians, in turn, are inclined to trust the advice of KOLs, Front Groups, and other seemingly independent sources of objective medical information. But by engaging in the conduct described herein, Defendants co-opted those sources of information in order to convince prescribing physicians—and through them, patients and Plaintiff—that opioids were medically necessary to treat chronic non-cancer pain. This was especially so given Defendants' deliberate targeting of non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate the false, deceptive, and materially misleading claims being promoted to them.

358. Defendants' conduct directly, proximately, and grievously injured Plaintiff, causing him to spend years as an opioid addict and suffer physical, non-physical, economic, and non-economic damages as a result. To the extent Plaintiff paid for his opioid prescriptions, he would not have done so but for Defendants' illegal conduct; likewise, Kevin Schwartz would have not moved forward with his opioid prescriptions at all, but for Defendants' illegal conduct.

359. As such, Defendants have engaged in fraudulent, deceptive, unlawful, and unfair business practices in violation of the OCSPA.

360. No public policy justifies Defendants' misconduct, including the Defendants' decades' long misinformation campaign, which made it wholly unreasonable to expect that

Plaintiff could have avoided his injuries. Plaintiff requests that this Court enter an order awarding judgment in Plaintiff's favor to compensate him for injuries sustained as a result of Defendants' consumer fraud and unfair practices, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just. Plaintiff also requests an award of $200 in liquidated damages for each Defendant-manufactured prescription he received following his accident.

COUNT III
UNJUST ENRICHMENT
(On Behalf of Plaintiff Kevin Schwartz)

361. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

362. A claim of unjust enrichment requires a plaintiff to demonstrate that "(1) a benefit conferred by a plaintiff upon a defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by the defendant under circumstances where it would be unjust to do so without payment." *Filo v. Liberato*, 2013-Ohio-1014, ¶ 35, 987 N.E.2d 707, 720 (internal quotations omitted).

363. Defendants' negligent, intentional, malicious, oppressive, illegal, and unethical acts, omissions, and wrongdoing entitle Plaintiff Kevin Schwartz to the disgorgement of profits received from all prescription opioid sales made to him.

364. Defendants' manufacturing, marketing, distribution, and sale of prescription opioids was done in violation of the basic duties and rules governing these activities, unjustly enriching Defendants while causing extraordinary harm to Plaintiff.

365. Plaintiff conferred benefits on Defendants, including payments for opioids manufactured by Defendants for sale. These benefits were known to and accepted by

Defendants, and inured to their profit. Retention of these benefits would be deeply inequitable in light of the false and misleading marketing and omissions of Defendants that caused Plaintiff to pay for opioids he would not have purchased, but for the Defendant-induced belief that they were safe for long-term use. Thus, Defendants have been unjustly enriched by their deceptive practices.

366. It would be inequitable under these circumstances for Defendants to be allowed to retain these benefits without compensating Plaintiff for their value. The enrichment Defendants experienced was without justification.

367. As such, Plaintiff Kevin Schwartz respectfully requests this Court award judgment in his favor, including declaratory relief that Defendants were unjustly enriched by their conduct described above, injunctive relief requiring Defendants to cease engaging in such conduct, ordering Defendants to disgorge their unjustly-obtained profits to Plaintiff, and awarding such other relief as this Court may deem just.

COUNT IV
CIVIL CONSPIRACY
(On Behalf of Plaintiff Kevin Schwartz)

368. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

369. A civil conspiracy is an independent tort in Ohio, consisting of "(1) a malicious combination, (2) involving two or more persons, (3) causing injury to person or property, and (4) the existence of an unlawful act independent from the conspiracy itself." *Strama v. Allstate Ins.*, 2015-Ohio-2590, ¶ 35.

370. Defendants acted tortiously in concert with each other in pursuit of a common goal: the pursuit of ever-greater profits from the sale of prescription opioids in Plaintiffs' community and throughout the country through a misinformation campaign.

371. Defendants agreed to, and did, pursue a common strategy of fabricating a market for long-term use of opioids by minimizing the risks of opioids, overstating their efficacy, and denigrating competing products. This agreement is evidenced by Defendants' co-promotion and sponsorship of KOLs and Front Groups who promulgated their misleading information about opioids. As part of their agreements with one another, Defendants agreed with Front Groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy, and that Defendants would provide support for Front Group's deceptive statements, including the dissemination of misleading messaging about opioids.

372. On information and belief, Defendants agreed to, and did, engage in a civil conspiracy that necessarily required—as a consequence of their conduct—making fraudulent misrepresentations, violating the OCSPA, and committing unjust enrichment through the unlawful distribution of opioids to Plaintiff and actively working to broaden the market for prescription opioids on false grounds. Defendants worked to weaken regulatory enforcement of pharmaceutical distribution and are highly coordinated through trade groups such as the Pain Care Forum. Given the level of coordination of their legal activities, and the scale of their illegal activities, the Defendants intended, agreed, and knew that the public—including Plaintiff and his doctors—would be misled about the risks and benefits of opioids.

373. The particular dates and times of Defendants' agreement cannot be known because this information is known only to Defendants. Indeed, this information has been hidden, because obfuscation and secrecy are essential to the success of the conspiracy.

374. Defendants unlawfully marketed prescription opioids in Plaintiff's community and throughout Ohio in furtherance of this conspiracy.

375. Their conduct was malicious, purposeful, intentional, and unlawful, and proximately caused (or substantially contributed to) the direct and foreseeable consequences of this conduct: a boom in opioid abuse, addiction, overdose, and death in Plaintiff's community, which included Plaintiff's becoming addicted to prescription opioids for years.

376. Plaintiff respectfully requests this Court enter an order awarding judgment in his favor to compensate him for injuries sustained as a result of Defendants' misconduct, for restitution of any money acquired as a result thereof, and awarding such other relief as this Court may deem just.

377. Plaintiff also requests this Court enter an order awarding relief by declaring that Defendants' activities constituted a civil conspiracy, enjoining Manufacturer Defendants from engaging in any further activities constituting civil conspiracy, and providing injunctive relief requiring Defendants to abate any harm caused by their civil conspiracy.

COUNT V
LOSS OF CONSORTIUM
(On Behalf of Plaintiff Stephanie Schwartz)

378. Plaintiff Stephanie Schwartz incorporates the foregoing allegations as if set forth herein.

379. In Ohio, it is well established that:

> [A] wife has a cause of action for damages for loss of consortium against a person who, either intentionally or negligently, injures her husband and thereby deprives her of the love, care and companionship of her husband ... "Consortium" consists of society, services, sexual relations and conjugal affection, which includes companionship, comfort, love and solace.

Bowen v. Kil-Kare, Inc., 63 Ohio St. 3d 84, 91, 585 N.E.2d 384, 391 (1992).

380. As set forth herein, Plaintiff Kevin Schwartz was injured by Defendants' tortious conduct, which included both intentional conduct and negligence, conduct in violation of the OCSPA, unjust enrichment, and a civil conspiracy.

381. As a result of Defendants' conduct, Kevin Schwartz became addicted to prescription opioids, and begin living a life defined by addiction, to the detriment of both him and his marriage. Stephanie Schwartz was near-completely deprived of her husband's love, care, companionship, society, services, sexual relations, and conjugal affection. At least ninety percent of the time, her husband was virtually a shell of himself.

382. Through and as a direct and proximate result of its conduct, Defendants deprived Stephanie Schwartz of her husband's love, care, and companionship. She is entitled to damages and all other remedies available at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Kevin Schwartz respectfully requests that this Court enter an Order:

A. Declaring that Defendants have acted negligently;

B. Directing Defendants to pay all damages caused by their negligent actions to Plaintiff Kevin Schwartz;

C. Declaring that Defendants have engaged in acts in violation of the OPLA;

D. Directing Defendants to pay all damages available to Plaintiff Kevin Schwartz under the OPLA for their violations;

E. Declaring that Defendants have engaged in acts in violation of the OCSPA;

F. Directing Defendants to pay all damages caused by violations of the OCSPA, including an award of liquidated damages;

G. Declaring that Defendants have been unjustly enriched by their conduct;

H. Directing Defendants to pay restitution of all benefits and disgorge all profits unjustly retained to Plaintiff Kevin Schwartz;

I. Declaring that Defendants have engaged in an unlawful civil conspiracy;

J. Directing Defendants to pay all damages caused to Plaintiff Kevin Schwartz by their civil conspiracy;

K. Declaring that Defendants caused Plaintiff Stephanie Schwartz's loss of her husband Kevin Schwartz's consortium;

L. Directing Defendants to pay all damages caused to Plaintiff Stephanie Schwartz attendant to the loss of her husband's society, services, sexual relations and conjugal affection, which includes companionship, comfort, love and solace;

M. Awarding punitive damages as appropriate;

N. Awarding injunctive relief as necessary to protect the interests of Plaintiffs;

O. Awarding Plaintiffs their reasonable litigation expenses and attorneys' fees, to the extent allowable under applicable law;

P. Awarding Plaintiffs pre- and post-judgment interest to the extent allowable under applicable law; and

Q. Award any and all other relief the Court deems appropriate and just.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury in this matter.

Respectfully submitted,

KEVIN SCHWARTZ and STEPHANIE SCHWARTZ,

Date: December 20, 2018

By: /s/ Daniel R. Karon
One of Plaintiffs' Attorneys

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*Admission *pro hac vice* to be sought